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Supreme Court, U.S.
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IN THE

Supreme Court of the United States

GREGORY W. BARAN, M.D.,

Petitioner,

v.

MEDICAL DEVICE TECHNOLOGIES, INC.,

Respondent.

ON PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether 35 U.S.C. § 112, ¶ 6 permits a patent claim expressed as a "means . . . for performing a specified function" to be construed to require functions not recited in the means clause.

PARTIES TO THE PROCEEDING

The petitioner here, and plaintiff-appellant in the Federal Circuit, is Gregory W. Baran, M.D. Dr. Baran, an individual, is the real party in interest.

The respondent here, and defendant-appellee in the Federal Circuit, is Medical Device Technologies, Inc. Defendants Amt Sverige, Ab (formerly known as Amedic), Ascendia Ab, Gedon Ab, and Anders H. Weilandt, originally named in the District Court case, were not parties to the appeal and are not parties to this proceeding.

RULE 29.6 CORPORATE DISCLOSURE STATEMENT

Dr. Baran is an individual residing in Novelty, Ohio.

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OPINION BELOW

The opinion of the U.S. Court of Appeals for the Federal Circuit is reported at 616 F.3d 1309 (Fed. Cir. 2010). App. C, 5a-22a. The order denying rehearing is attached at App. B, 3a-4a.

The opinions of the United States District Court for the Northern District of Ohio are reported at 519 F.Supp.2d 698 (N.D. Ohio 2007) (*Markman* Order) (App. F, 110a-178a) and 666 F.Supp.2d 776 (N.D. Ohio 2009) (Summary Judgment Order) (App. E, 24a-109a).

JURISDICTION

The U.S. Court of Appeals for the Federal Circuit entered its judgment on August 12, 2010 and denied Dr. Baran's combined petition for rehearing and rehearing en banc on October 5, 2010. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(a)(1) (2010).

The district court had jurisdiction to hear Dr. Baran's claim for patent infringement under 28 U.S.C. § 1338(a) (2010). The Federal Circuit had jurisdiction to hear Dr. Baran's appeal under 28 U.S.C. § 1295(a)(1) (2010).

STATUTORY PROVISION INVOLVED

"An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed

to cover the corresponding structure, material, or acts described in the specification and equivalents thereof." 35 U.S.C. § 112, ¶ 6 (2010).

INTRODUCTION

This case raises a discrete, yet fundamental issue of interpretation of the 1952 Patent Act: what is the proper scope of a claim written in the "means-plus-function" format sanctioned by 35 U.S.C. § 112, ¶ 6? Is the function of such a claim defined by what is literally recited in the means clause? Or, can a "means-plus-function" claim be construed to require unrecited functions?

35 U.S.C. § 112, ¶ 6 was included in the 1952 Act to address the doubt cast on functional claiming language by this Court's decision in *Halliburton Oil Well Cementing Co. v. Walker*, 329 U.S. 1 (1946). Prior to that decision, claiming inventions as "means for" performing a specified function had been common and had received the apparent approval of this Court in *Continental Paper Bag Co. v. Eastern Paper Bag Co.*, 210 U.S. 405 (1908). By providing specific sanction to "means-plus-function" claiming as an option available to inventors, the 1952 Act wove this claiming practice into the fabric of the patent law. Countless patents have issued with claims based on the Patent Act's mandate.

The decision of the Federal Circuit panel in this case—construing a "means for retaining" as a means for *releasing* and retaining—casts a shadow over inventions claimed according to the mandate of 35 U.S.C. § 112, ¶ 6 equally as great as that cast by the

Halliburton case sixty-four years ago. By countenancing the construction of means-plus-function clauses to include functions not expressly recited in the clause, the panel decision conflicts with the plain language of the statute and the decisions of other Federal Circuit panels deeming such construction impermissible. As such, the decision disrupts the settled expectations of patent owners and applicants by creating uncertainty over the scope of claims written in the sanctioned format.

In the fifty-eight years since its enactment, this Court has not addressed the proper interpretation of 35 U.S.C. § 112, ¶ 6 or those claims written according to it. This is an ideal case in which to do so because there is no argument that the "means for" clause at issue expressly recites only a retaining function. Therefore, the question is simply presented: does 35 U.S.C. § 112, ¶ 6 permit adoption of a function other than that specified in the "means for" clause or not? Because the courts are, under this Court's decision in *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996), the arbiters of the meaning of patent claims, it is all the more critical for the Court to provide an answer to this question.

STATEMENT OF THE CASE

A. The Claimed Invention

Dr. Baran is an individual inventor and practicing physician. His U.S. Patent No. 5,025,797 (filed June 25, 1991) ("the '797 Patent"), the patent-in-suit, is directed to automated biopsy instruments. App. C at 6a (616 F.

3d at 1311). Each biopsy instrument has a needle including a stationary stylet (a probe) and a movable cutting cannula (a tube that is inserted into the body) that, in use, slides over the stylet to sever tissue and capture a sample for biopsy. App. C at 6a-7a (616 F. 3d at 1311); *see also* '797 Patent at col. 5, ll. 37–40.

The cannula is movable via a guide between a charged position and a discharged position. App. C at 6a-7a (616 F. 3d at 1311); *see also* '797 Patent at col. 8, ll. 9–13. A coil spring biases the guide towards the discharged position. App. C at 6a (616 F. 3d at 1311); *see also* '797 Patent at col. 7, ll. 12–16. When the guide is moved against the coil spring to the charged position, a latching projection of a "release lever" engages a shoulder of the guide, thereby retaining the guide in the charged position. App. C at 6a (616 F. 3d at 1311); *see also* '797 Patent at col. 7, ll. 23–27.

To discharge the instrument, the operator depresses a finger rest portion of the "release lever," which releases the lever by raising the latching projection of the lever. Raising the latch projection disengages the shoulder of the guide, and the compressed spring then drives the cannula forward over the stationary stylet. App. C at 7a (616 F. 3d at 1311); *see also* '797 Patent at col. 7, ll. 61–68; Col. 8, ll. 1–4.

B. Proceedings Below

The asserted claim of the '797 patent recites a biopsy instrument comprising, among other elements, "a release means for retaining the guide in the charged position." It is undisputed that this "means for

retaining" limitation is a means-plus-function clause that falls under the statutory mandate for such claims found in 35 U.S.C. § 112, ¶ 6. App. F at 144a (519 F.Supp.2d at 715-16).

Under *Markman v. Westview Instruments*, 517 U.S. 370 (1996), claim construction is a matter for the court's determination. *Id.* at 388. Thus, after holding a so-called *Markman* hearing, the district court issued a claim construction order construing the disputed terms and phrases. App. F at 110a-178a (519 F. Supp. 2d 698). In this Order, the district court recognized that the means for retaining limitation has a "very clearly defined function" of "retaining the guide in the charged position." App. F at 148a (519 F. Supp. 2d at 717). In spite of this recognition, the district court concluded that the prefatory adjective "release" required a second function, which the court then added to the "clearly defined" function. App. F at 149a (519 F. Supp. 2d at 717-18). Specifically, the district court construed the claim to require a function of "retaining the guide in the charged position *and releasing, or setting free,* the guide from the charged position." App. F at 150a (519 F. Supp. 2d at 718) (emphasis added). The district court subsequently granted summary judgment of noninfringement based on this erroneous modification of the recited function. App. E at 78a-108a (666 F.Supp.2d 776, 803-20).

On appeal, a panel of the Federal Circuit affirmed the district court's construction of the means for retaining limitation and the corresponding finding of noninfringement, reasoning that the patent "contemplated" the unrecited releasing function:

> The patent [specification] does not recite a biopsy instrument that retains indefinitely without release; rather the contemplated function is to retain for the express purpose of producing a spring-loaded release on demand.

App. C at 19a (616 F.3d at 1317). In other words, even though the means clause does not specify a releasing function, the court construed the claim to require such a function. The Federal Circuit denied Dr. Baran's combined petition for rehearing and rehearing en banc without opinion. App. B at 3a-4a.[1]

REASONS FOR GRANTING THE PETITION

1. THE FEDERAL CIRCUIT PANEL'S DECISION CONFLICTS WITH THE PATENT ACT'S MANDATE ALLOWING INVENTIONS TO BE EXPRESSED AS "MEANS FOR" PERFORMING A SPECIFIED FUNCTION AND WITH THE FEDERAL CIRCUIT'S OWN PRECEDENT INTERPRETING THAT MANDATE

The last paragraph of Section 112 allows inventors to claim their inventions in functional terms without reciting structure:

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1. Although the district court found that the accused device performs a releasing function, it held that the structure in the accused device used to perform that function is non-infringing under the limited coverage provided by § 112, ¶ 6. App. E at 100a-108a (666 F.Supp.2d at 814-820). The Federal Circuit concurred. App. C. at 20a-21a (616 F.3d at 1317-18).

> An element in a claim for a combination may be expressed as a means or step for performing *a specified function* without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

35 U.S.C. § 112, ¶ 6 (emphasis added).

Although there is little legislative history on this provision, the impetus behind it appears to be well-settled: namely, that it was added by the 1952 Patent Act to address a perceived cloud cast over so-called "means-plus-function" claiming by this Court's decision in *Halliburton Oil Well Cementing Co. v. Walker*, 329 U.S. 1 (1946), which invalidated claims written in functional language for failing to reveal specific structures. *See* 3-8 Donald S. Chisum, *Chisum on Patents* § 8.04[1][d] (2010). Prior to that case, "claim language in means-plus-function style had been common . . . and had received the apparent approval of the Supreme Court in *Continental Paper Bag Co. v. Eastern Paper Bag Co.*, [210 U.S. 405 (1908)]." *Id.* In discussing the relationship between § 112, ¶ 6 and the doctrine of equivalents, this Court alluded to the provision's origins when it noted that it "was enacted as a targeted cure to a specific problem[.]" *Warner-Jenkinson Co., Inc. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 28 (1997). Beyond this brief discussion of the provision in *Warner-Jenkinson*, however, this Court has not, in the fifty-eight years since enactment, directly addressed the meaning of § 112, ¶ 6.

Section 112, ¶ 6 clearly allows a claim drafter to use a phrase with a "means," a "specified function," and no recitation of structure. The paragraph goes on to state a rule of construction that the unrecited *structure* corresponding to the specified function is limited to that structure described in the specification and its equivalents. The *function*, however, is that "specified" in the means-plus-function clause.

That the function of a "means for" claim element is the function specified in the means clause is unremarkable as a matter of statutory interpretation and seems to have engendered no debate in the case law. In fact, the Federal Circuit appears to have only addressed this obvious interpretation of the statute in reversing those few district court decisions that have strayed from it.

In *Micro Chem. Inc. v. Great Plains Chem. Co., Inc.*, 194 F.3d 1250 (Fed. Cir. 1999), the Federal Circuit reversed a district court decision construing, *inter alia*, the function of a "weighing means for determining the weights of selected additives" as "sequential and cumulative weighing[.]" *Id.* at 1254, 1258. The Federal Circuit rejected this construction of the function, finding that "the properly identified function . . . signaled by the preposition 'for,' is 'determining the weights of selected additives.'" *Id.* at 1258. According to this decision, "[t]he statute does not permit limitation of a means-plus-function claim by adopting a function different from that explicitly recited in the claim" and the district court had violated that precept by "incorporating unrecited functional limitations into the claims." *Id.* The court warned of the cascading effect of such an error, noting that "an error in identification of

the function can improperly alter the identification of structure in the specification corresponding to that function." *Id.* The possible mischief is self-evident: because a claim written in this format covers (under 35 U.S.C. § 112, ¶ 6) only "the corresponding structure . . . described in the specification and equivalents thereof," erroneously identifying the claimed function compounds the possibilities for unduly narrowing the coverage of the claim.

Two years later, in *Generation II Orthotics, Inc. v. Med. Tech., Inc.*, 263 F3d 1356 (Fed. Cir. 2001), the Federal Circuit reiterated the *Micro Chemical* holding concerning the proper way to identify the function in a means-plus-function clause. The disputed means clause in this case was a "joint means . . . for allowing controlled medial and lateral inclination of each rigid arm relative to the pivotable joint." *Id.* at 1361. The district court construed the phrase to require control "'throughout the range of motion of the brace' or dynamic control." *Id.* at 1363. In reversing the district court, the Federal Circuit stated that the "joint means . . . *literally recites* merely 'allowing controlled medial and lateral inclination of each rigid arm relative to the pivotable joint'" and the district court's construction "impermissibly . . . adopt[ed] a function different from that explicitly recited in the claim." *Id.* at 1364 (emphasis added). The Federal Circuit rejected the argument that the patent specification implied that the joint means performed only dynamic control as contrary to the teachings of *Micro Chemical*. And it concluded with an admonition to future panels: "we must take great care not to impermissibly limit the function [in a means-plus-function limitation] by adopting a function different from that explicitly recited in the claim." *Id.* at 1364–65.

The panel in the instant case failed to heed this admonition. Even though the explicitly recited function of the biopsy instrument's "release means" is "retaining the guide in the charged position," the court affirmed the district court's addition of a second, unrecited, releasing function. Thus, what Dr. Baran had chosen to claim as a singular function for this element was impermissibly converted into a compound function. And just as the *Micro Chemical* court had warned, the panel found non-infringement when comparing the structure corresponding to this erroneously identified function with the structure of the accused device.

The panel decision also fails to acknowledge the questions raised concerning the proper identification of function in a means clause written in the statutory format either as a matter of statutory interpretation or as construed by the Federal Circuit's opinions in *Micro Chemical* and *Generation II*. Instead, the panel discusses two other cases—*Signtech USA, Ltd. v. Vutek, Inc.*, 174 F.3d 1352 (Fed. Cir. 1999) and *Al-Site Corp. v. VSI Int'l, Inc.*, 174 F.3d 1308 (Fed. Cir. 1999)—that address a different point: in what circumstances claims that were *not* written in "means-plus-function" format may be interpreted as functional claims under the statute.[2] Neither case addresses construction of a claim element written according to the mandated "means for"

2. A means-plus-function claim is considered narrower in certain respects because of the bargain struck in the statute that limits coverage of claims in that format to structures disclosed in the specification (and equivalents of those structures). *See* Peter S. Menell et al., Federal Judicial Center, *Patent Case Management Judicial Guide* § 5.2.3.5, at 5-69 to -70 (2009). Therefore, infringement defendants often contend that claims fall within the purview of Section 112, ¶ 6 even if a claim does not use the "means for" formulation. *See id.* at 5-70.

format with the function signaled by the preposition "for" followed by an expressly recited function.

The rationales the panel offers for its decision are also erroneous and do not support deviation either from the plain meaning of the statute or the Federal Circuit precedent interpreting it. The panel states that the patent does not contemplate "a biopsy instrument that retains indefinitely without release[.]" App. C at 19a (616 F.3d at 1317). But an inventor is not required to claim everything that is contemplated or suggested by the specification. *See Ventana Med. Sys. v. Biogenex Labs., Inc.*, 473 F.3d 1173, 1181-82 (Fed. Cir. 2006). Nor does the fact that the biopsy instrument described in the specification performs a function (releasing) that is *not* specified in the means clause allow the Federal Circuit to override the statute by adding that unrecited function to the function that *is* specified. The argument that the specification can alter the literal recitation of function in a means claim was soundly rejected as impermissible in *Generation II*. It also is inconsistent with the bedrock patent law principles that the claims not the specification define the invention (*see* 35 U.S.C. § 112,¶ 2) and that it is a "cardinal sin" to import limitations from the specification into the claims. *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1324 (Fed. Cir. 2002).

Finally, this case did not present, as the district court feared, an irreconcilable conflict between two fundamental rules of patent law. The district court recognized that "to use the term 'release' to inform the definition of the function arguably 'impermissibly limit[s] the claim by adopting a function different from that explicitly recited'" but concluded that "to ignore the

term 'release' would run afoul of the rule that '[w]e must give meaning to all words in [the] claims[.]'" App. F at 148a (519 F. Supp. 2d 698, 717) (citations omitted).

But this case posed no such Hobson's choice. Construing the function solely as "retaining the guide member" does not require ignoring the adjective "release." In the specification, the word "release" is used as an adjective modifying the word "lever" to indicate a releasable element. In the embodiments in the patent, the lever releases by the press of a finger. App. C at 7a (616 F.3d at 1311); *see also* '797 Patent col. 7, ll. 61–68. Construing a "release lever" as a releasable lever, *i.e.*, a lever *that releases*, as Dr. Baran argued, would have given meaning to the word release without impermissibly adopting a function different from that recited in the means clause. By converting the word "release" into a second functional requirement, the panel dishonored the statute and violated the Federal Circuit's own precedent promising vigilance against that very type of abuse.

Because the panel's holding conflicts with the Federal Circuit's own precedent, as well as with the plain language of 35 U.S.C. § 112, ¶ 6, it warrants review by this Court.

II. THE PANEL DECISION CREATES UNCERTAINTY FOR CURRENT PATENT APPLICANTS AND FOR COUNTLESS PATENTEES WHOSE ISSUED CLAIMS WERE DRAFTED ACCORDING TO THE PLAIN MEANING OF THE STATUTE

The plain language of 35 U.S.C. § 112, ¶ 6 provides inventors with a framework for claiming their inventions in functional language without the need to recite structure, so long as they specify what that claimed function is. Countless existing and pending patents include such claims on the understanding that the statute means what it says and that the Federal Circuit would, as promised, "take great care not to . . . adopt[] a function different from that explicitly recited in the claim." *Generation II*, 263 F.3d at 1364-65.

Yet, the panel's decision in this case breaks that promise and, in so doing, casts a cloud of uncertainty over previously issued and currently pending claims written in the statutorily-mandated means-plus-function format, a cloud as foreboding as that cast by the *Halliburton* case and removed by the 1952 Act. By upsetting the expectations of untold numbers of patentees, as well as those members of the public reviewing the claims in the context of potential infringement, the decision creates uncertainty and undermines the value of investments. This consideration is particularly important in cases, such as the present one, "involving property . . . . rights, where reliance interests are involved." *Payne v. Tennessee*, 501 U.S. 808, 828 (1991).

Even if the decision were more narrowly interpreted to apply only to those "means for" claims that are preceded by a modifier such as the "*release* means" here, the decision's potential impact is still large. This drafting style is common enough that means claims drafted with a modifying term preceding the means clause can fairly be described as ubiquitous. Indeed, the claims at issue in *Halliburton* ("echo receiving means"), *Micro Chemical* ("weighing means"), and *Generation II* ("joint means") mimic this hallmark drafting style. Therefore, even under this narrower reading, the uncertainty the panel decision creates is sufficiently broad to warrant this Court's review.

III. THIS CASE IS A GOOD VEHICLE FOR RESOLVING THE QUESTION PRESENTED

This is an ideal case through which to resolve the proper interpretation of § 112, ¶ 6 as it pertains to the identification of function in a patent claim drafted in the very "means for" format expressly sanctioned by the statute.

The question presents itself as a purely legal issue, independent of the facts of this particular case, and will thus allow for a ruling of universal application. There is no dispute in this case over what function the patentee specified in the "means for" clause at issue. Instead, the question is whether, regardless of the absence of any dispute over the specified function, the claim can be interpreted to include a function that the "means for" clause does not specify but that the courts below imported from elsewhere in the patent. In other words, the discrete, yet significant legal question is starkly

presented: Does 35 U.S.C. § 112, ¶ 6 permit adoption of a function other than that specified in the "means for" clause or not?

In the fifty-eight years since the enactment of the Patent Act, the Supreme Court has not addressed the interpretation of this important provision of the law. This case presents an ideal opportunity for the Court both to address the proper interpretation of 35 U.S.C. § 112, ¶ 6 and to provide certainty on an issue that affects large numbers of patent holders and current and future applicants.

CONCLUSION

For the foregoing reasons, the petition for writ of certiorari should be granted.

Respectfully submitted,

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APPENDIX A — JUDGMENT OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT MANDATED OCTOBER 12, 2010

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

2010-1058

GREGORY W. BARAN, M.D.,

Plaintiff-Appellant,

v.

MEDICAL DEVICE TECHNOLOGIES, INC.,

Defendant-Appellee,

and

AMT SVERIGE, AB (formerly known as AMEDIC) and ASCENDIA AB,

Defendants,

and

GEDON AB and ANDERS H. WEILANDT,

Defendants.

JUDGMENT

ON APPEAL from the United States District Court for the Northern District of Ohio in Case No. 04-CV-1251.

Appendix A

This CAUSE having been heard and considered, it is ORDERED and ADJUDGED:

AFFIRMED

ENTERED BY ORDER OF THE COURT

/s/

Jan Horbaly, Clerk

DATED AUG 12, 2010

APPENDIX B — ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT FILED OCTOBER 5, 2010

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

2010-1058

GREGORY W. BARAN, M.D.,

Plaintiff-Appellant,

v.

MEDICAL DEVICE TECHNOLOGIES, INC.,

Defendant-Appellee,

and

AMT SVERIGE, AB (formerly known as AMEDIC) and ASCENDIA AB,

Defendants,

and

GEDON AB and ANDERS H. WEILANDT,

Defendants.

Appeal from the United States District Court for the Northern District of Ohio in case no. 04-CV-1251, Judge Kathleen M. O'Malley.

ORDER

NOTE: This order is nonprecedential.

Appendix B

A combined petition for panel rehearing and for rehearing en banc having been filed by the Appellant, and the petition for rehearing, having been referred to the panel that heard the appeal, and thereafter the petition for rehearing en banc having been referred to the circuit judges who are in regular active service,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for panel rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the petition for rehearing en banc be, and the same hereby is, DENIED.

The mandate of the court will issue on October 12, 2010.

FOR THE COURT,

/s/

Jan Horbaly
Clerk

Dated: 10/05/2010

cc: Steven M. Auvil
Monica L. Thompson

BARAN V MEDICAL DEVICE TECH, 2010-1058
(DCT - 04-CV-1251)

APPENDIX C — DECISION OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT DECIDED AUGUST 12, 2010

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

2010-1058

GREGORY W. BARAN, M.D.,

Plaintiff-Appellant,

v.

MEDICAL DEVICE TECHNOLOGIES, INC.,

Defendant-Appellee,

and

AMT SVERIGE, AB (formerly known as AMEDIC) and ASCENDIA AB,

Defendants,

and

GEDON AB and ANDERS H. WEILANDT,

Defendants.

Appeal from the United States District Court for the Northern District of Ohio in case No. 04-CV-1251, Judge Kathleen M. O'Malley.

DECISION

Appendix C

STEVEN M. AUVIL, Benesch, Friedlander, Coplan & Aronoff, LLP, of Cleveland, Ohio, argued for plaintiff-appellant. With him on the brief was BRYAN J. JAKETIC.

MONICA L. THOMPSON, DLA Piper LLP (US), of Chicago, Illinois, argued for defendant-appellee. With her on the brief was STEVEN J. REYNOLDS.

Before BRYSON, GAJARSA, and PROST, *Circuit Judges*.

BRYSON, *Circuit Judge*.

Dr. Gregory W. Baran filed suit against the defendants (collectively, "MDTech"), alleging infringement of U.S. Patent Nos. 5,025,797 and 5,400,798. The '798 patent is a continuation-in-part of the '797 patent, and both patents are directed to automated biopsy instruments. For the reasons stated below, we affirm the district court's entry of judgment in favor of MDTech as to both patents.

I

In the automated biopsy instruments that are the subject of this appeal, the biopsy needle is composed of a stationary stylet and a retractable cannula that slides over the stylet. After the cannula is pulled back against a coil spring and cocked in the "charged" position, the stylet is inserted into the patient's body. When the

cannula is released from the charged position, the spring drives the cannula forward over the inserted stylet to cut out a biopsy sample. The entire needle is then removed from the patient and the biopsy sample is extracted from the cannula.

The claimed devices are charged by pulling back an external guide (to which the cannula is attached) along the shaft until the guide locks in place. The locking function is performed by a lever (22 in Figure 4, below) that slides into a slot. Pressing the other end of the lever releases the lock and allows the spring to send the cannula forward over the stylet.

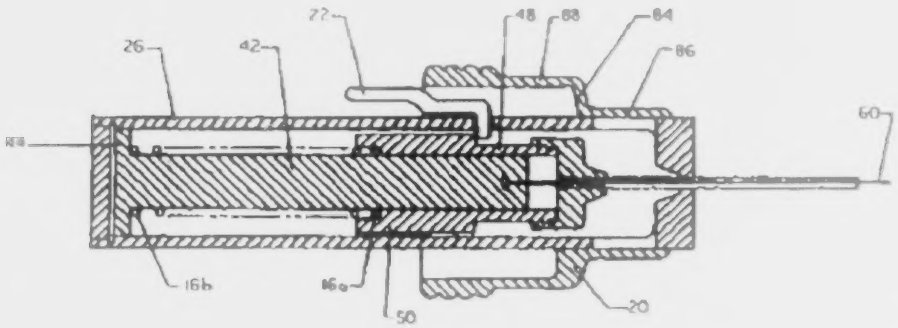


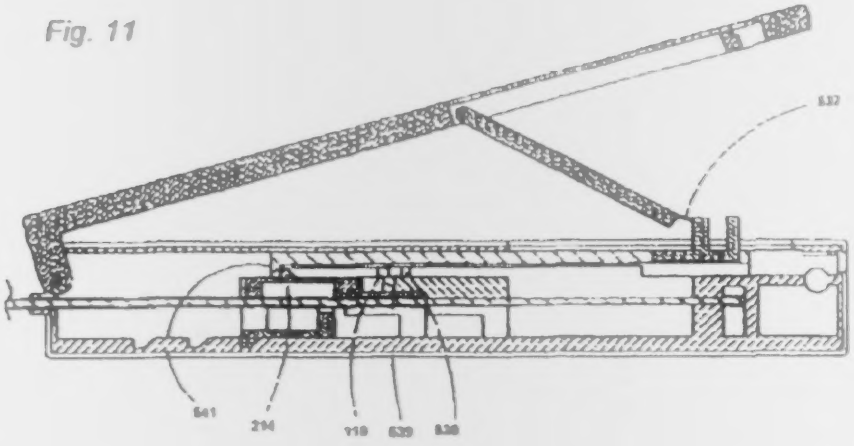
FIG. 4

'797 patent, fig. 4; '798 patent, fig. 4.

In MDTech's accused device, the BioPince Full Core Biopsy Instrument ("BioPince"), the instrument is charged by means of a slider-crank mechanism. The user

lifts the crank arm away from the device, which pushes a connected slider unit to the front of the device where it latches onto the cannula guide. The user then presses the crank arm down toward the device, which pushes both the slider and the cannula guide to the rear of the device. A locking tab inserts through a slot in the crank arm and locks the device in the charged position. Pressing a trigger button at the back of the device detaches the cannula guide from the slider, allowing the spring to send the cannula and its guide forward. The following figure is taken from MDTech's patent and is an accurate represen-tation of MDTech's commercial device:

Fig. 11



U.S. Patent No. 6,322,523 B2, fig. 11.

Claim 2, the only asserted claim of the '798 patent, reads as follows (emphases added):

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An apparatus for acquiring biopsy specimens, the apparatus comprising in combination:

a) a biopsy actuator;

b) a cannula having a predetermined inner diameter and having a distal end for insertion into a patient and having an opposing proximal end, said proximal end having a *first connector means* secured thereto;

c) a stylet means . . . said stylet means being *detachable* from said cannula;

d) said biopsy actuator comprising a *second connector means for releasably and fixedly engaging the first connector means*, wherein the first connector means and the second connector means are movable as a unit during acquisition of the biopsy specimen,

e) said biopsy actuator comprising means for rap-idly advancing the distal end of said cannula beyond the distal end of the stylet means to acquire a core biopsy specimen.

The district court construed the term "detachable" in claim 2 to mean that "the stylet is capable of being separated or withdrawn from the cannula without loss or damage." The court found it significant that the specification disclosed both a reusable embodiment and a single-use embodiment, and that only the stylet of the reusable embodiment was described as being "detachably engaged" while the stylet of the single-use

embodiment was de-scribed as being "adhesively bonded." The court rejected the argument that an adhesively bonded stylet could also be detachably engaged. Moreover, although the court acknowledged that the construction of "without loss or damage" might exclude the single-use embodiment from claim 2, the court noted that it was not necessary for each claim to cover every embodiment of the patent.

The district court construed the term "releasably" in a similar manner, as requiring "separation without loss or damage." The court noted that claim 2 recited the second connector means as being "releasably engag[ed]," and that the specification described the same structure as being "detachably affixed." Accordingly, the court reasoned that the patentee had used the terms "releasably" and "de-tachably" with a similar meaning in mind. Based on that cross-usage, the court applied essentially the same construction to both terms.

Following the issuance of the claim construction order, Dr. Baran entered a stipulation acknowledging that he could not prove infringement of the '798 patent under the "without loss or damage" construction as applied to the terms "first connector" and "second connector." Dr. Baran reserved his right to appeal the claim construction order.

As for the '797 patent, the district court granted summary judgment of noninfringement on the ground that the accused BioPince device failed to satisfy two limitations relating to the charging mechanism. Claim 7, the only asserted claim of the '797 patent, reads in

pertinent part (emphases added): "A biopsy instrument comprising . . . a manually operable charging *member* for moving the guide to the charged position against the urging of the coil spring, and a *release means for retaining the guide in the charged position.*"

The district court first considered whether the term "member" should be limited to a single component or whether it could encompass a multi-component structure. The court ultimately adopted a construction that allowed for the use of multiple components, but only if those components operated in unison and not in a serial chain of events. The court determined that the various compo-nents of the slider-crank mechanism in the BioPince device did not act in unison to move the cannula into the charged position, and it therefore concluded that the device did not satisfy the "charging member" limitation of the '797 patent.

In addition, the court concluded that the BioPince device did not satisfy the limitation reciting a "release means for retaining the guide in the charged position." The court construed that limitation to be in means-plus-function format and to have two functions—retaining the guide in the charged position and releasing the guide from the charged position. The court then addressed whether the BioPince device had corresponding structure that performed the retention/release function. Dr. Baran contended that the relevant corresponding structure in the accused device was the combination of the crank arm and the locking tab that holds the crank arm in the charged position. Inserting the locking tab through the appropriate slot in the crank arm would retain the guide in the charged position;

pulling the crank arm up and snapping it out of the locked position would release the cannula guide from the charged position. Therefore, Dr. Baran argued, the crank arm and the locking tab constituted a structure in the accused device that performed both the retention function and the release function. The court accepted that argument over MDTech's objection that the only proper method of release was the trigger mechanism, which did not perform the retention function. The court ruled that the crank arm qualified as a means for performing the release function in the BioPince device because discharging the device in that manner did not require physical alteration of the device. Nevertheless, the court found no infringement because it concluded that the crank arm and locking tab structure was substantially different from the corresponding lever structure disclosed in the specification of the '797 patent.

II

A

In his challenge to the district court's construction of the '798 patent, Dr. Baran advocates a definition for the terms "detachable" and "releasably" that does not include the "without loss or damage" condition. Dr. Baran objects to that condition because it excludes the single-use embodiment from the asserted patent claim and therefore precludes his infringement claim against the BioPince, which is a single-use device.

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As an initial matter, we accept Dr. Baran's assertion that the '798 patent "never discloses a stylet that is joined to a cannula." The specification indicates that the stylet 60 is attached to a support rod 14, and that the cannula 66 is attached to a spring guide 18. The full needle is then assembled by placing a coil spring "coaxially" onto the stylet and placing the cannula "telescopically" over the stylet and coil spring. The cannula remains an independent component that slides freely over the stylet.

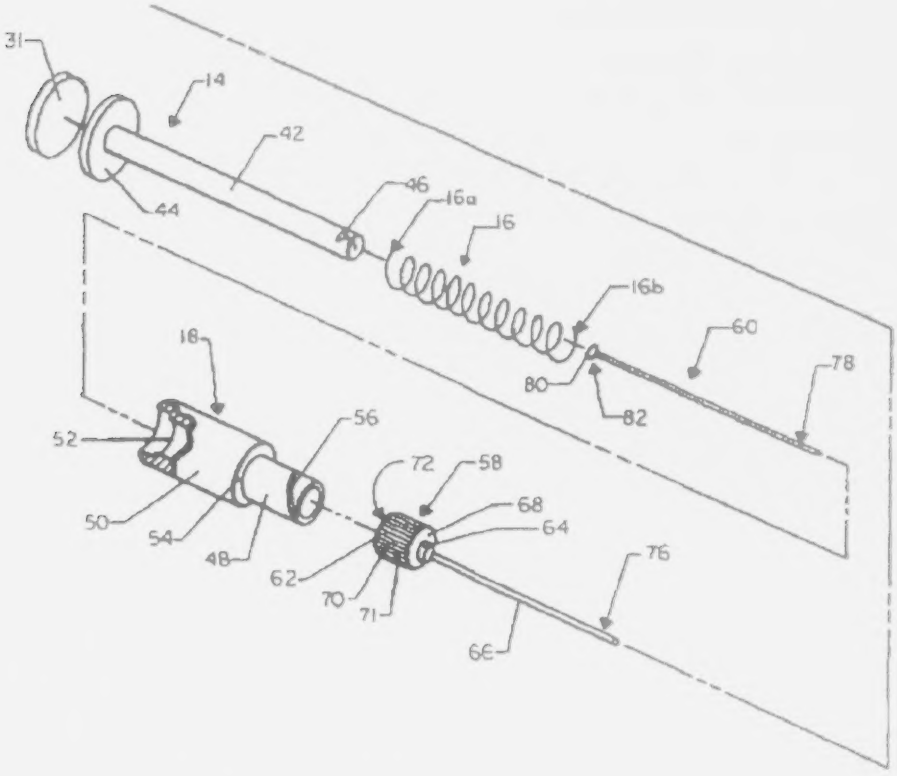

FIG. 1

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The fact that the stylet is not attached to the cannula, however, is not favorable to Dr. Baran. If anything, it lends further credence to the district court's construction of "detachable" as meaning "separation without loss or damage," because the stylet and cannula as described in the specification are readily separable without loss or damage.

Of greater significance is the different language used by the patentee to distinguish the single-use embodiment from the reusable embodiment. In describing the reusable embodiment, the patent states that "the stylet 60 is received and detachably engaged within the clevis 46 of the spring guide 18. The thread 74 on the inner surface 72 of the collar 62 is engaged with the thread 56 on the spring guide 18 to secure the cannula mount 58 to the spring guide." '798 patent, col. 7, ll. 42-46. Figure 1 shows that the stylet is inserted into a notched recess on the support rod from which it can be easily removed,[1] and that the cannula is screwed onto the spring guide from which it too can be easily removed.

By contrast, in describing the single-use embodiment, the patent states that the assembly of the device is "quite similar" except that "the stylet 262 is adhesively bonded within the recess 246, and the base 262 of the cannula mount 258 is similarly secured within the bore 255a." '798 patent, col. 10, ll. 22-27. Figure 5,

1. Although the specification states that the stylet is inserted into the clevis of the "spring guide," Figure 1 clearly shows that the clevis is located on the support rod.

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which corresponds to the single-use embodiment, shows that the clevis is absent from the support rod, and that the screw threads are absent from the spring guide. Instead, the stylet and the cannula are glued permanently into the support rod and the spring guide, respectively.

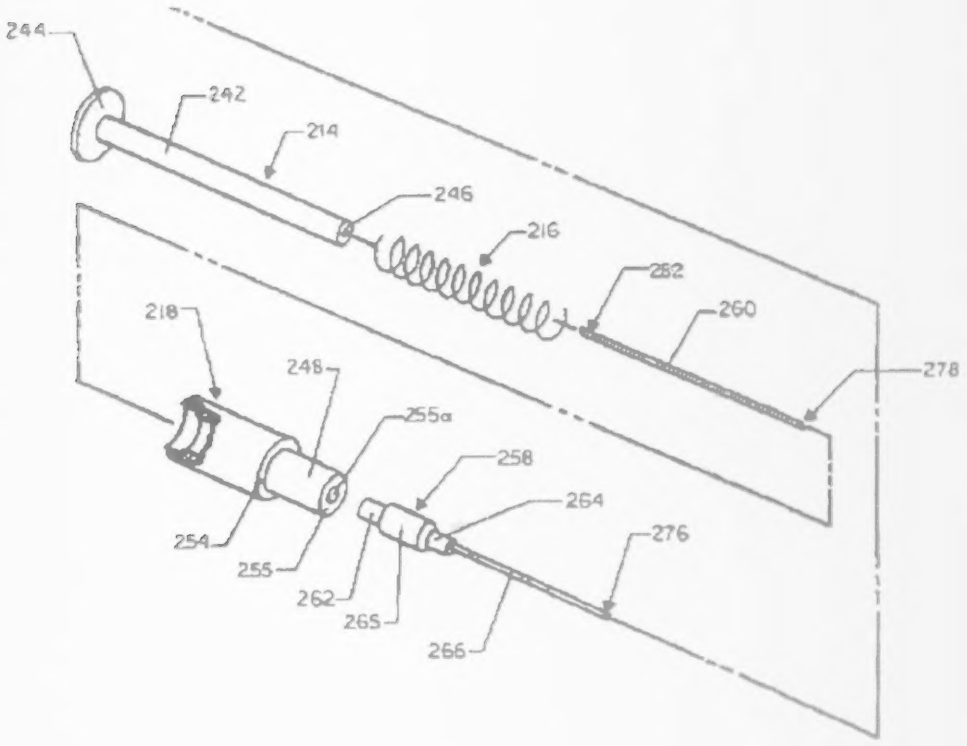

FIG. 5

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The patentee used the term "detachably" in the specification to draw a direct contrast between the removable components of the reusable embodiment and the adhesively bonded components of the single-use embodiment. That usage effectively concedes that adhesively bonded components—including the single-use embodiment—are not "detachable" components within the meaning of the patent. We agree with the district court that "[t]his distinction suggests that the patentee intended 'detach-able' to mean capable of removal or separation without breaking or causing damage through the necessary use of undue force." *Baran v. Med. Device Techs., Inc.*, 519 F. Supp. 2d 698, 724 (N.D. Ohio 2007); *see also K-2 Corp. v. Salomon S.A.*, 191 F.3d 1356, 1365 (Fed. Cir. 1999) ("Screws, unlike rivets and [adhesive] laminates, are meant to be unscrewed, that is, to be removed. A rivet or a laminate, to the contrary, is meant to remain permanent, unremovable unless one is bent on breaking the permanent structure apart."). Incorporating the "without loss or damage" condition into the claim construction has the additional advantage of comporting with the plain meaning of "detachable," as expressed by the several dictionary definitions cited by the district court.

We also agree with the district court that the terms "releasably" and "detachable" have the same meaning in the '798 patent. Dr. Baran argues that the use of different terms implies that they have different meanings, *see CAE Screenplates Inc. v. Heinrich GmbH*, 224 F.3d 1308, 1317 (Fed. Cir. 2000), but that implication is overcome where, as here, the evidence

indicates that the patentee used the two terms interchangeably. *See Tehrani v. Hamilton Med., Inc.*, 331 F.3d 1355, 1361 (Fed. Cir. 2003).

In a final attempt to bring the single-use embodiment within the scope of the asserted claim, Dr. Baran argues that the district court's claim construction improperly excluded a preferred embodiment and ignored the Summary of the Invention. There is no force to either of those arguments. It is not necessary that each claim read on every embodiment. In this instance, while claim 2 reads on only the reusable embodiment, a different claim of the '798 patent (claim 18) reads on both the single-use and the reusable embodiments. *See Helmsderfer v. Bobrick Washroom Equip., Inc.*, 527 F.3d 1379, 1383 (Fed. Cir. 2008) ("It is often the case that different claims are directed to and cover different disclosed embodiments."); *Intamin Ltd. v. Magnetar Techs., Corp.*, 483 F.3d 1328, 1336-37 (Fed. Cir. 2007) ("[A] claim need not cover all embodiments."). As for the excerpt from the Summary of the Invention, it simply repeats verbatim the claim language that the "stylet means is . . . detachable from the cannula" and that the "second connector . . . releasably and fixedly engages the first connector." '798 patent, col. 3, ll. 50-60. The fact that those claim terms were used in the Summary does not mean that they must be read to encompass all the embodiments of the invention.

Because we do not disturb the district court's construction of "releasably," or the related constructions of "first connector means" and "second connector means," Dr. Baran's stipulation of noninfringement of the '798 patent remains effective.

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B

Dr. Baran also appeals the two grounds on which summary judgment was entered as to the '797 patent. We conclude that no reasonable juror could find that MDTech's BioPince device satisfies the means-plus-function limitation of "release means for retaining the guide in the charged position." That determination is sufficient to affirm the district court's judgment of noninfringement; accordingly, we do not address Dr. Baran's additional arguments regarding the "charging member" limitation.

In construing a means-plus-function claim, the district court must first determine the claimed function and then identify the corresponding structure in the written description of the patent that performs that function. *Applied Med. Res. Corp. v. U.S. Surgical Corp.*, 448 F.3d 1324, 1332 (Fed. Cir. 2006). In order to prove literal infringement of a means-plus-function claim, the plaintiff must show that the accused device performs the recited function through structure that is the same as or equivalent to the corresponding structure set forth in the specification. 35 U.S.C. § 112, ¶ 6.

Dr. Baran argues that the district court erred in construing the claim to require both a release function and a retention function. According to Dr. Baran, "release" precedes the "means for" clause and therefore "is a modifier of the limitation, rather than a functional recitation." He urges that "release" should be construed to mean "releasable," which he explains is a

characteristic and not a function. Presumably, Dr. Baran believes that distinction to be significant because a characteristic would describe something the structure is merely capable of performing, not something the structure must perform.

We agree with the district court that the claim language recites both a release function and a retention function. Dr. Baran's argument regarding the placement of the term "release" is unavailing. The relevant inquiry is whether the term at issue is purely functional. *See Signtech USA, Ltd. v. Vutek, Inc.*, 174 F.3d 1352, 1356 (Fed. Cir. 1999) (construing "ink delivery means" to be equivalent to "means for ink delivery" because "ink delivery" was purely functional language); *Al-Site Corp. v. VSI Int'l, Inc.*, 174 F.3d 1308, 1318 (Fed. Cir. 1999) ("[W]hen it is apparent that the element invokes purely functional terms . . . the claim element may be a means-plus-function element despite the lack of express means-plus-function language."). In the context of the '797 patent, the term "release" is not an idle description but a vital function to be performed by the means-plus-function element. The patent does not recite a biopsy instrument that retains indefinitely without release; rather, the contemplated function is to retain for the express purpose of producing a spring-loaded release on demand. The claim language ties both functions to the same means-plus-function element, so it is appropriate that the element be construed accordingly.

In the alternative, Dr. Baran argues that the question whether the crank arm and locking tab structure fulfills the retention/release limitation raises

a disputed issue of material fact and was not suitable for resolution on summary judgment. The district court concluded that the accused structure was substantially different from the disclosed structure because the BioPince device requires the locking tab to flex in a yielding manner for the release to occur, while the patented invention relies on a lever that must be rigid in order to pivot on its fulcrum. Dr. Baran disagrees with the district court's characterization and claims that both structures flex to release the guide. He bases that contention on two passages from the '797 patent: the first states that one end of the lever is "flexibly secured" to the other end by a "spot weld," i.e., the fulcrum; the second states that the release lever is "flexibly welded" to the outer casing.

Again, we find that the district court did not err in concluding that the accused structure was not equivalent to the structure described in the specification. The two structures rely on opposing principles: the lever facilitates the release by clearing the retention means from the path of the guide, while the locking tab mechanism achieves release only by overcoming the full resistance of the retention means. Because of that structural difference, the lever must be rigid to release the guide, while the locking tab must be flexible to do the same. The references to "flexibility" that Dr. Baran cites from the patent refer to the fact that the lever remains free to pivot flexibly along the fulcrum, not that the lever itself is made of flexible material. Indeed, it would be impossible to operate a lever if it were made of highly elastic material, just as it

would be impossible to bypass a locking tab if it were made of stiff, unyielding material. Accordingly, we concur with the district court that the accused structure is substantially different from the disclosed structure and therefore does not infringe pursuant to section 112, paragraph 6.

III

We also find no merit in Dr. Baran's argument that the district court erred by striking portions of the declaration that he submitted in opposition to MDTech's motion for summary judgment. The declaration was a detailed, 22-page report attesting to Dr. Baran's qualifications as an expert, describing the asserted patent claims and the accused device, and offering extensive opinion testimony in support of his theories of infringement. The court found that the "vast majority of [Dr.] Baran's declaration is opinion testimony based on 'scientific, technical, or other specialized knowledge within the scope of Rule 702,'" and that it was, "as a practical matter, an expert report in which he provides his infringement opinion." *Baran v. Med. Device Techs., Inc.*, 666 F. Supp. 2d 776, 779 n.2 (N.D. Ohio 2009). The court further found that Dr. Baran had not identified himself as an expert, as required by Federal Rule of Civil Procedure 26(a)(2), and that his "expert report" was submitted well after the deadline for exchanging expert reports established by the court's case management plan. As a result, the court held that it would not consider Dr. Baran's declaration "to the extent it provides expert testimony." *Id.*

Dr. Baran argues that his report should not have been ruled untimely, because he was not a witness "retained or specially employed to provide expert testimony" and therefore was not required to prepare a written report pursuant to Federal Rule of Civil Procedure 26(a)(2)(B). But the fact that Dr. Baran was not required to prepare a written report in the first instance does not mean that he was exempt from the district court's case management deadlines once he opted to submit a written report. The district court had broad discretion to fashion its case management deadlines, and those deadlines applied to all expert reports, including ones not required by rule. *See Clarksville-Montgomery County Sch. Sys. v. U.S. Gypsum Co.*, 925 F.2d 993, 998 (6th Cir. 1991); *see also Esposito v. Home Depot U.S.A., Inc.*, 590 F.3d 72, 77-78 & n.2 (1st Cir. 2009). The district court was justified in excluding Dr. Baran's report to enforce compliance with those deadlines.

AFFIRMED

APPENDIX D — JUDGMENT ENTRY OF THE UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF OHIO EASTERN DIVISION DATED SEPTEMBER 30, 2009

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

Case No. 1:04cv1251

GREGORY W. BARAN, M.D.,

Plaintiff,

v.

MEDICAL DEVICE TECHNOLOGIES, INC., et al.,

Defendants.

JUDGMENT ENTRY

For the reasons stated in the Court's order of this date granting the Defendant's motion for summary judgment, this case is **DISMISSED**.

IT IS SO ORDERED.

/s/ _____
KATHLEEN McDONALD O'MALLEY
UNITED STATES DISTRICT JUDGE

Dated: September 30, 2009

APPENDIX E — MEMORANDUM AND ORDER OF THE UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF OHIO EASTERN DIVISION DATED SEPTEMBER 30, 2009

UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF OHIO EASTERN DIVISION

Case No. 1:04cv1251

GREGORY W. BARAN, M.D.,

Plaintiff,

v.

MEDICAL DEVICE TECHNOLOGIES, INC., et al.,

Defendants.

JUDGE KATHLEEN O'MALLEY

MEMORANDUM AND ORDER

In this patent action, Defendant Medical Device Technologies, Inc. ("MDTech") has filed a *Motion for Summary Judgment of Noninfringement* (Doc. 164, "MSJ"). By way of its motion, MDTech argues that there is no genuine issue of material fact that MDTech does not infringe claim 7 of U.S. Patent No. 5,025,797 (the "'797 Patent"). Plaintiff Gregory W. Baran, M.D. ("Baran") opposes the motion, which has been fully briefed and is now ripe for adjudication.[1] For the reasons articulated below, MDTech's motion for summary

1. MDTech's MSJ was filed on December 22, 2008 (Doc. 164). Baran filed a response in opposition to the motion for summary judgment on January 26, 2009 (Doc. 171), and, with

Cont'd

judgment is **GRANTED** and this case is **DISMISSED**.[2]

Cont'd

MDTech's consent, filed a corrected brief in opposition on February 12, 2009 (Doc. 179, "Opp'n Br."). MDTech filed a reply in support of its MSJ on February 12, 2009 (Doc. 180, "Reply Br.").

2. Also ripe and pending before the Court is Baran's motion for leave to file a sur-reply brief (Doc. 181, "Mt. for Leave to File Sur-Reply"), which MDTech opposes (Doc. 182). Both parties acknowledge that a sur-reply is not appropriate under the rules without leave of Court, which may be granted to allow the moving party to address new arguments raised in the reply brief. After full consideration of the parties' briefs, Baran's Mt. for Leave to File Sur-Reply is **DENIED**; the Court will not consider Does. 181, 182 or 185 in analyzing MDTech's MSJ. The Court disagrees with Baran's claim that the arguments in the Reply Br. are "new." Each was raised and addressed in the MSJ, Opp'n Br., and Reply Br. The central issue Baran wishes to address by way of sur-reply is whether the Court should strike the declaration he personally submitted in support of his Opp'n Br., which includes a report setting forth his infringement opinions, and numerous exhibits thereto. Baran identified this issue in footnote 1 of his Opp'n Br. and argued that it is appropriate for the Court to consider his declaration. MDTech responded with the suggestion that the Court strike the declaration. Therefore, the issue has been framed for the Court's consideration; it is not new. Similarly, the infringement arguments presented in the proposed sur-reply simply expand upon arguments Baran already raised. Although the proposed sur-reply brief might provide a more thorough or refined articulation of Baran's position with respect to the arguments he identifies, the purpose of a sur-reply is not to permit re-argument after additional reflection.

Cont'd

Appendix E

Cont'd

As for Baran's declaration, the Court will only consider those portions of the declaration that are authorized by the Federal Rules of Evidence. *Id.* The vast majority of Baran's declaration is opinion testimony based on "scientific, technical, or other specialized knowledge within the scope of Rule 702." Fed. R. Evid. 701. Although Baran did not identify himself as an expert as required by Rule 26(a)(2) of the Federal Rules of Procedure and the Court's Case Management Plan (Doc. 25), he is attempting to present expert testimony by way of a declaration pursuant to Rule 56(e) of the Federal Rules of Procedure. *See* Fed. R. Civ. P. 26(a)(2) ("[A] party must disclose to the other parties the identity of any witness it may use at trial to present evidence under Federal Rule of Evidence 702, 703, and 705."). Rule 56(e) requires that affidavits (and declarations) submitted in opposition to summary judgment comply with the rules of evidence. His declaration is, as a practical matter, an expert report in which he provides his infringement opinion. Baran's "expert report" was submitted well after the deadline for exchanging expert reports established by the Case Management Plan for this matter (Doc. 25) and without notice to MDTech. Accordingly, to the extent it provides expert testimony, the Court has not considered it in analyzing MDTech's MSJ. Baran cites *Ekstam v. Ekstam*, 2007 U.S. Dist. LEXIS 64868, 2007 WL 2571968 (E.D. Mo. 2007), for the proposition that the Court should excuse his failure to comply with the procedural prerequisites to providing expert testimony. The Court is not persuaded by *Ekstam*. It is not binding authority, and it is readily distinguishable because the *Ekstam* court found that the affidavit at issue substantially satisfied Fed. R. Civ. P. 56(c).

Appendix E

I. BACKGROUND[3]

This is a patent infringement lawsuit relating to a biopsy instrument manufactured, distributed, and sold by MDTech. The allegedly infringing biopsy instrument is known as the BioPince (R) Full Core Biopsy Instrument ("BioPince"). In his Complaint,[4] Baran alleges that MDTech willfully infringed both U.S. Patent No. 5,400,798 (the "'798 Patent") and the '797 Patent by manufacturing, distributing, and selling the BioPince.

A. PROCEDURAL HISTORY

After briefing and a hearing, the Court issued an Opinion & Order construing the disputed claim limitations of the patents at issue pursuant to *Markman v. Westview Instruments*, 517 U.S. 370, 116 S. Ct. 1384, 134 L. Ed. 2d 577 (1996) ("*Markman* Opinion"). Although his Complaint assert generally that MDTech has directly or indirectly infringed one or more claims of the '797 and '798 Patents, Baran narrowed the asserted claims to claim 7 of the '797 patent and claim 2 of the '798 Patent

3. The background of this case (including an account of procedural oddities relating to the participation of additional defendants) is set forth in some detail in the Court's *Markman* Opinion (Doc. 132 at 2-3). The Court expressly incorporates that description into this Opinion & Order. In the interest of judicial efficiency, the Court will not repeat it here, except to the extent necessary to address the motions presently pending.

4. "Complaint" refers to Dr. Baran's *Second Amended Complaint for Willful Patent Infringement* (Doc. 60).

during the claim construction process. Further, after the *Markman* Opinion issued, the parties filed a joint stipulation stating that, in light of the Court's construction of certain limitations in claim 2 of the '798 Patent, Baran "admits that he cannot prove that the . . . BioPince, . . . as made, used, offered for sale, or sold by [MDTech] is an infringement of claim 2 of the '798 patent." (Doc. 145, Jt. Stipulation Re: '798 Patent.)[5] Consequently, the only infringement allegations remaining after the Joint Stipulation are those relating to claim 7 of the '797 Patent.

B. ISSUE

The issue on summary judgment is whether, in view of the Court's construction of the three debated limitations of claim 7 of the '797 Patent, MDTech is entitled to judgment of noninfringement as a matter of law because there is no genuine issue of material fact with respect to infringement as to at least one limitation of the claim.

C. BACKGROUND OF THE INVENTION: THE '797 PATENT & THE BIOPINCE

A basic understanding of the patent and allegedly infringing device — the BioPince — is necessary to understand and address this issue.

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5. The Joint Stipulation also states that Baran objects to the Court's construction of claim 2 of the '798 Patent, and notes that both parties reserve the right to appeal the Court's *Markman* Opinion.

Appendix E

1. Biopsy Instruments & the '797 Patent

In the *Markman* Opinion, the Court described biopsy instruments generally, and the '797 Patent specifically, in the "Overview of the Invention" section. In pertinent part, that section is set forth below.[6]

A. Overview of the Invention[7]

> As mentioned at the outset, Baran's patents are directed at an automated biopsy instrument. To give context to Baran's invention and the problems it was intended to remedy, the Court first reviews biopsy instruments in general before addressing Baran's specific invention.[8]
>
> A biopsy instrument, generally, is a device for removing a sample of tissue from a human being or animal for diagnosis. Prior to the

6. The footnotes in the quoted section of the *Markman* Opinion appear as footnotes 6-8 of this Opinion & Order. To identify these footnotes as quotations, they are indented.

7. The claims at issue in this case, although from two different patents, refer to the same invention. The '798 patent is a later filed Continuation-in-Part of the '797 patent, but the new matter introduced in the '798 patent is not at issue here. The portions of the '797 specification and '798 specification relevant to the Court's analysis, therefore, are nearly identical. To avoid redundancy, the Court cites only to the '797 specification in providing a general overview of the invention.

8. The following information was gleaned by the Court from the parties' briefs, the parties' oral arguments, the prior art disclosed in the patents at issue, and the patents themselves.

advent of biopsy instruments, tissue specimens primarily were obtained through invasive exploratory surgery. Biopsy instruments enabled medical professionals to obtain tissue samples with less risk of trauma and damage to a patient. Most contemporary biopsy instruments remove the tissue sample through the use of a two part needle set comprised of a stylet, which is a slender probe or wire, and a cannula, which is a hollow tube that surrounds the stylet and can be inserted into the body. The cannula, and sometimes the stylet, are sharp or pointed so that they are capable of cutting through or piercing tissue.

There are two primary methods of obtaining a tissue specimen that the parties described in their briefs and at the *Markman* hearing. Each method involves the use of a different type of needle. . . .

The . . . method [used in the BioPince] involves a full-core needle, which, as the name implies, employs a stylet that does not contain a slot or gap. With this method, the cannula extends beyond the stylet and is inserted into the tissue. The tissue sample fills the hollow portion of the cannula. Once the needle is withdrawn from the patient, the stylet can then be advanced into the cannula to eject the sample from the cannula. Typically, this method requires some sort of negative

pressure or suction to ensure that the specimen actually stays inside the cannula when it is withdrawn. Counsel for MDTech analogized this method to putting a straw in a cola bottle - a user needs to put his finger over the straw when it is removed in order to capture some cola in the straw. (Transcript from *Markman* Hearing (hereinafter, "Tr."), at 76.)

. . .

In different biopsy instruments, movement of the stylet and cannula can be manual, semi-automated, or automated. A manually operated biopsy device, of course, requires the user to move the cannula and the stylet by hand. The semi-automated and automated biopsy instruments, however, contain some sort of part or mechanism to move either the cannula, the stylet, or both. . . . The benefits of the semi-automated and automated devices over the manual devices are that the cutting motion is swifter, which causes a cleaner cut, does less damage to the surrounding tissue, and shortens the length of the procedure; the automated devices are more accurate; and there is less risk of inherent human error in operating the cannula and stylet.

With that background, the Court now turns to the patents at issue in this case. The '797

patent was filed on March 29, 1989 and issued on June 25, 1991 . . . . As the prior art above shows, the invention disclosed in these patents was not the first for an automated biopsy instrument; it was an improvement on existing automated instruments. In the Background of the Invention, the patent identifies certain problems with instruments known at the time, primarily related to the ease of use and risk of accident. Specifically, the patent explains that "the various automated biopsy instruments presently known tend to be heavy, difficult to manipulate, and incorporate biasing mechanisms[9] which are either complicated in construction or require undue force to operate." ('797 patent, col. 3, l. 8-12.) In addition, the Background of the Invention identifies the possibility of "inadvertent movement or torque," especially in the case of instruments that permit or require elements to be manually adjusted prior to advancement of the cannula. (*Id.*, col. 3, l. 14-20). Likewise, some instruments contain a moveable stylet that extends beyond the rear of the instrument, leaving it vulnerable to accidental impact and inadvertent advancement into the body. (*Id.*, col. 2, l. 37-47.) Finally, the Background of the Invention notes that the known instruments have

9. Biasing mechanisms are the mechanisms that charge and discharge the cannula and the stylet for advancement into the tissue. The parties agree on the meaning of this phrase.

exposed triggers or releases that actuate the movement of the cannula or stylet, thus further creating the risk of accidental advancement of the cannula. (*Id.*)

To address those perceived problems, the '797 patent provides an instrument with a stationary stylet that, once mounted to the instrument, cannot be moved inadvertently or otherwise. (*Id.*, col. 3, l. 30-35.) It also describes a guide on which a cannula can be mounted that can be manually moved to the charged position against the urging of a biasing mechanism such as a coil spring, and can be released to the discharged position, advancing in the direction of the stylet by a manually actuable release means. (*Id.*, col. 2, l. 35-44.) To address the problem of an exposed trigger or release, the patent describes that, "[i]n the preferred embodiments of the invention, a shield means is provided which is disposed to block or prevent inadvertent actuation of the release means." (*Id.*, col. 2, l. 58-60.) . . .

There are two basic embodiments in the '797 and '798 patents. One embodiment, depicted in Fig. 1 of both patents, relates to a reusable configuration that permits needle sets to be used and replaced, so that the instrument can be used multiple times for multiple patients. The second embodiment, depicted in Fig. 5 of

both patents, relates to a single use configuration that can be used on only one patient. An exploded view of the first embodiment, taken from Fig. 1, is shown [below]:

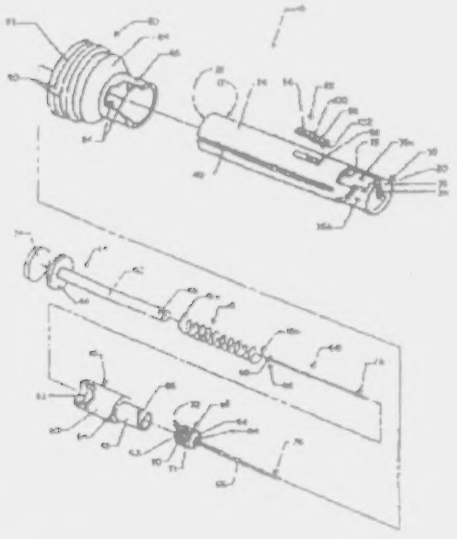

FIG. 1

The automated instrument **10** as shown in Fig. 1 includes the following primary components: an outer casing **12**; a support rod **14**; a coil spring **16**; a biopsy spring guide **18**; a safety cap **20**; a release lever **22**; and a needle **24**. ('797 patent, col. 4, l. 47-51.) A needle **24** is not shown in this illustration (it is shown in Figure 1A), but it comprises a stylet **60** and a cannula mount **58**, which, in turn, comprises a cylindrical collar **62**, a conical head **64**, and a cutting cannula **66**. (*Id.*, col. 4, l. 37-40.) . . .

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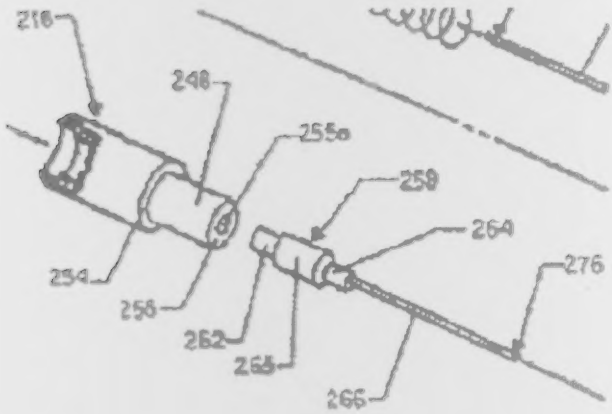
According to the Detailed Description of the Invention, the instrument is converted from the discharged mode to the charged-safety-on mode (meaning it is ready to fire, but there is a shield over the release) by retracting the safety cap **20** toward the rear end **28** of the tube **26**. (*Id.*, col. 7, l. 4-7.) This action causes the guide pins **94** to engage the annular external shoulder **54** of the spring guide **18** to retract the spring guide toward the base **44** of the support rod **14** and compress the coil spring **16**. (*Id.*, col. 7, l. 12-16.) In other words, according to that description, the charge is created when the safety cap is pulled backward and the guide pins on the inside of the safety cap structure catch the shoulder of the spring guide, which compresses the spring back toward the base. This action creates the charge that, once the release is pressed, causes the cannula to advance forward over the stylet.

As between Fig. 1 (the reusable embodiment) and Fig. 5 (the single use embodiment), the most significant difference for purposes of the Court's present analysis is the cannula mount, specifically the cannula mount's interaction with the spring guide. The relevant portion of Fig. 5 is shown to the right. As depicted, rather than have a screw-on feature like the cannula mount in Fig. 1, this embodiment has a plug-in type feature, where the cannula

mount 258 receives the cannula 266 on one end and plugs into the guide 218 by inserting the base 262 into a bore 255a in the guide.



These descriptions of the invention are meant to provide some background to the claims at issue in this case. The remaining elements of the invention will be discussed below, where applicable . . . .

(*Markman* Opinion at 9-16.) The figure below from the front page of the patent provides an overview of one embodiment of the '797 Patent in its charged-ready mode.

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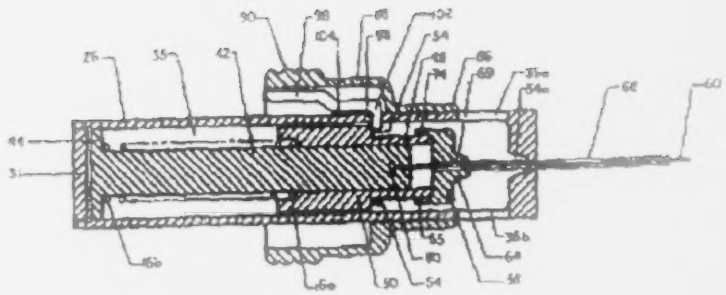

2. The BioPince

The BioPince is an automated biopsy instrument that uses a full-core needle. The figures below, Figure 1 from Baran's Opp'n Br. and Figure 1 from MDTech's MSJ, depicts one of the allegedly infringing models of the BioPince. [10]

10. Baran identifies two allegedly infringing models of the BioPince: Model No. 360-1080-01, which has a green cocking arm, and a later redesigned model with a blue cocking arm. (Opp'n Br. at 3.) The parties agree that these two models — the "green" and "blue" models — are identical for purposes of this Court's infringement analysis.

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[FOLDOUT]

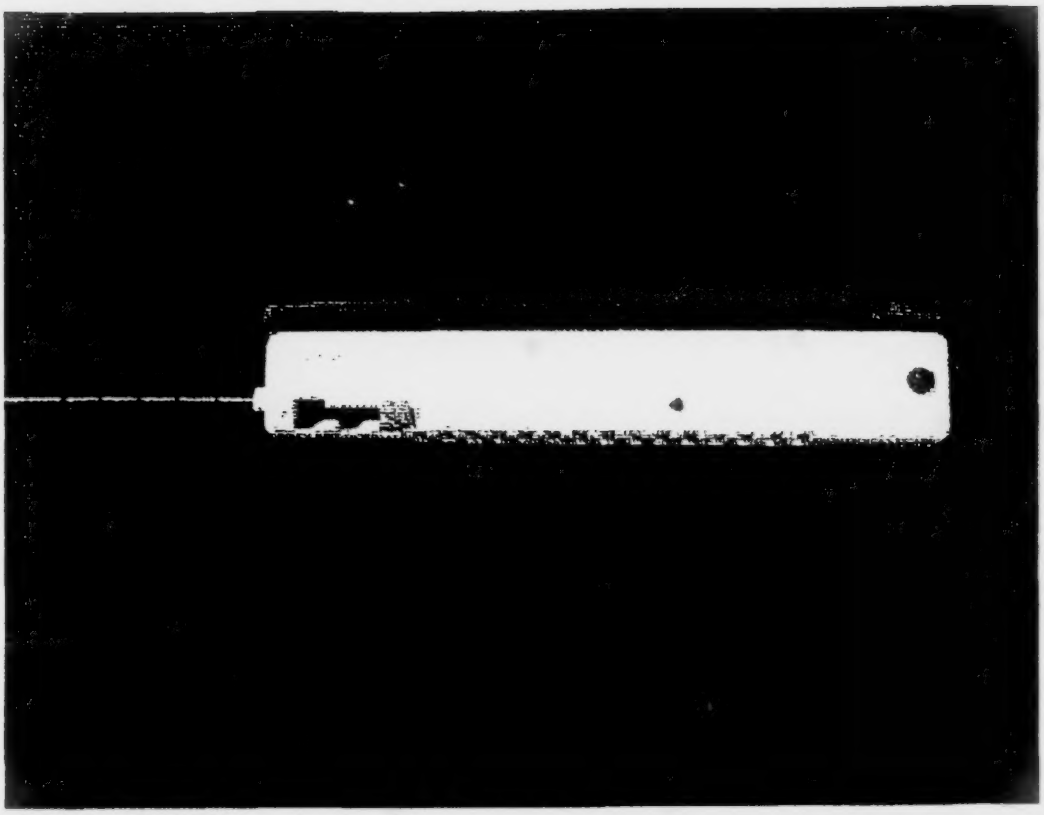

Figure 1 – Opp'n Br.

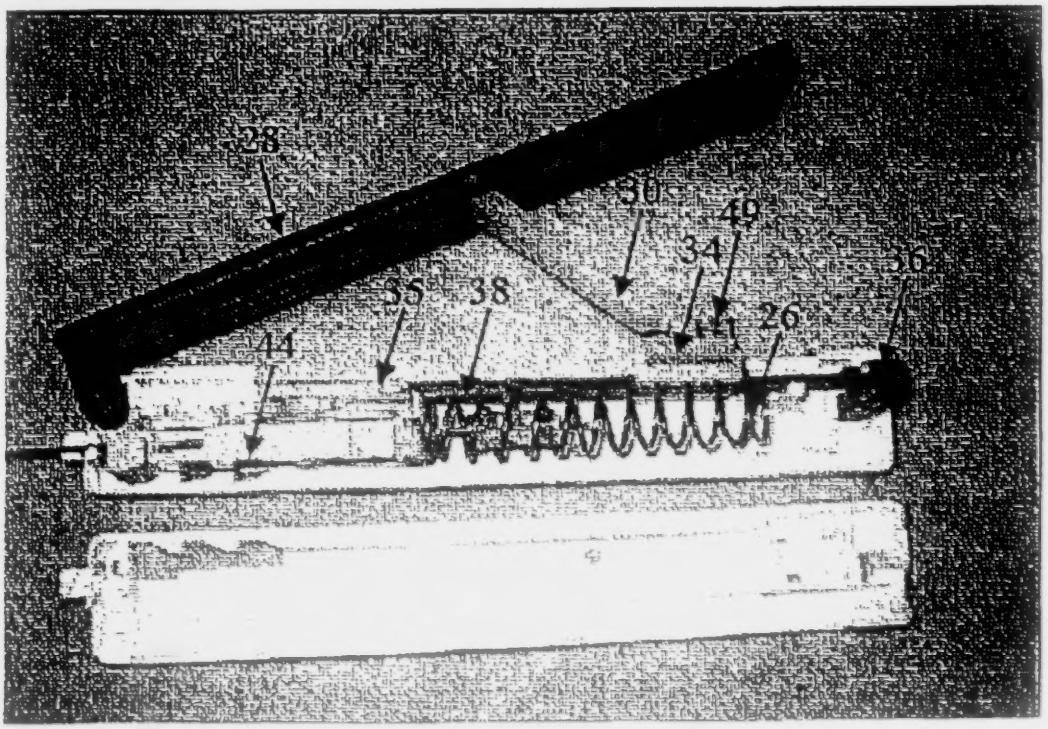

Figure 1 – MSJ

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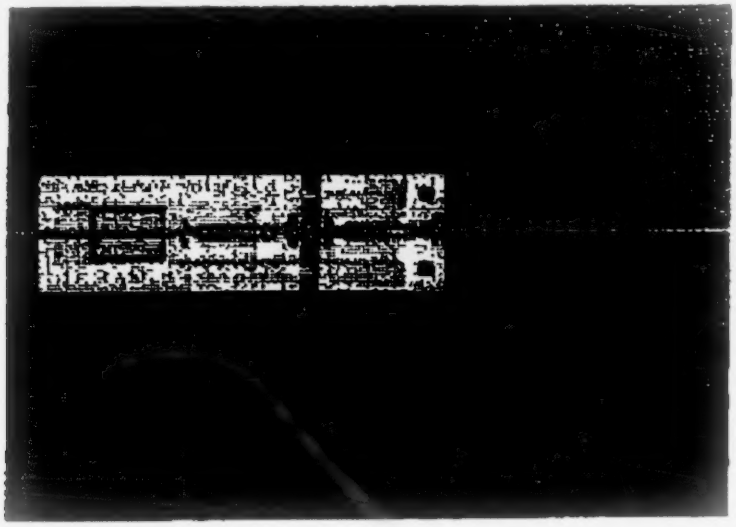
As illustrated by the figures above, the BioPince includes a white plastic casing housing the internal components of the device, and a needle, protruding from the casing on the left side of the figure. The needle consists of three components: (1) a solid stylet sharpened to a point at its distal end, inside (2) a hollow inner cannula (also referred to as a *cutting* cannula because the circumference of its distal end is sharpened for cutting through tissue), both of which are inside (3) a hollow outer tube. The stylet extends beyond the hollow outer tube and cannula in the direction opposite the distal end of the needle, and is attached to a plastic retaining block. The stylet extends through the center of the spring **26**. The cannula and the outer tube are attached to interlocking guides by a patch of adhesive; the outer tube is glued to the front guide while the cannula is glued to the back guide.



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The interlocking guides are connected such that they move together as the BioPince is placed into a charged[11] position and during the first part of the spring-propelled discharge.

The BioPince includes a crank arm 28 pivotally connected to the end of the casing directly above the point at which the needle protrudes from the casing. Along with several other components, including, but not limited to, the connecting rod 30, crank arm fixer 34, and slider link 35, the crank arm forms a mechanism[12] for charging the spring 26.

To charge the spring, the user holds the casing in one hand and lifts the crank arm away from the casing with the other until the locking groove in the slider link engages with the latching protrusion on the front guide. The sound of a "click" indicates that the locking groove has engaged with the latching protrusion. Then, the user pushes the crank arm toward the easing, thus compressing the spring between the back guide and the end of the housing containing the trigger button 36. The BioPince is charged when a second click indicates that the crank arm locking tab positioned on top of the crank arm fixer inserts through the slot in the crank arm and engages the shoulder of the slot, thereby locking the

11. Both parties describe the BioPince as "charged" when the spring is compressed such that, when released, its elastic potential energy propels the guides in the direction of the distal end of the stylet to take a biopsy sample.

12. This mechanism will be referred to as the "slider-crank mechanism" in this Memorandum & Order.

crank arm to the crank arm fixer. The BioPince can now be fired by moving the safety to the "fire" position and pressing the trigger button 36.

Pressing the trigger button pushes the distal end of the elongated release bar 38 toward the latching protrusion of the front guide. The distal end of the elongated release bar acts as an inclined plane inserted between the latching protrusion and slider link to release the cannula guides. Thus, pressing the trigger button releases the elastic potential energy from the compressed spring and propels the guides and cannula in the direction of the distal end of the needle, into the tissue to be sampled.

To retrieve the sample, the user completely removes the BioPince needle from the subject and charges the device again, causing the stylet to advance through the cannula and expel the tissue sample retained therein. This leaves the BioPince in the charged position, ready to take another tissue sample from the same subject. Therefore, the BioPince will ultimately be in the charged position after all biopsy samples have been retrieved.

D. THE COURT'S CONSTRUCTION OF THE LIMITATIONS OF CLAIM 7

In its *Markman* Opinion, the Court construed several limitations of claim 7 of the '797 Patent. Claim 7 of the '797 Patent provides as follows, with the terms the Court construed in bold.

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> 7. A biopsy instrument comprising an elongate hollow casing, a needle extending outwardly from the casing and having a cannula and a stylet received within the cannula, a stationary support mounted within the casing in fixed relation thereto and having means affixing the stylet thereto, a cannula guide, **a cannula mount affixing the cannula to the guide**, the guide being completely enclosed by the casing for reciprocating movement therewithin relative to the stationary support between a charged position, wherein the cannula is retracted in a direction away from the distal end of the stylet, and a discharged position, wherein the cannula is displaced from the charged position in the direction of the distal end of the stylet, a coil spring engaged between the stationary support and the guide for urging the guide toward the discharged position, **a manually operable charging member for moving the guide to the charged position against the urging of the coil spring, and a release means for retaining the guide in the charged position.**

('797 patent, col. 12, l. 54 - col. 13, l.5.) The Court construed the disputed terms in claim 7 of the '797 patent as follows:

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TERM	CONSTRUCTION
a cannula mount affixing the cannula to the guide	a structure or support which attaches or connects the cannula to the guide
a manually operable charging member for moving the guide to the charged position against the urging of the coil spring	a manually operable charging member that is used to create a charge or stored energy, the charging member configured to move the guide to the charged position against the urging of the coil spring
a release means for retaining the guide in the charged position	Means-plus-function claim in which the function is "retaining the guide in the charged position and releasing, or setting free, the guide from the charged position." structures corresponding to this function are: (1) for the reusable embodiment (Figs. 1 - 4A), the release lever 22, including the latching projection 102, the finger rest 96, mounting

> section 98, and connecting web 100, as well as the equivalents thereof; and (2) for the single use embodiment (Figs. 5-8A), the release lever 222, including the latching projection 302 and the mounting section 298, as well as the equivalents thereof

(*Markman* Opinion at 49-50.) Each of these claims is at issue on summary judgment and will be discussed further below.

II. DISCUSSION

A. THE LEGAL STANDARD FOR A MOTION FOR SUMMARY JUDGMENT

MDTech has moved for summary judgment of noninfringement under Rule 56 of the Federal Rules of Civil Procedure. (Doc. 164.) Under Rule 56(c), summary judgment should be granted "if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c); *see also Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 2009

U.S. App. LEXIS 20622, 2009 WL 2950226, *3 (Fed. Cir. Sept. 16, 2009). This standard applies in patent cases just as it does in other areas of law. *Nike, Inc. v. Wolverine World Wide, Inc.*, 43 F.3d 644, 646 (Fed. Cir. 1994).

In reviewing summary judgment motions, this Court must view evidence in the light most favorable to the non-moving party to determine whether a genuine issue of material fact exists. *Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 90 S. Ct. 1598, 26 L. Ed. 2d 142 (1970); *Ball Aerosol & Specialty Container, Inc. v. Limited Brands, Inc.*, 555 F.3d 984, 991 (Fed. Cir. 2009); *CenTra, Inc. v. Estrin*, 538 F.3d 402, 412 (6th Cir. 2008); *Ricoh Co., Ltd. v. Quanta Computer, Inc.*, 550 F.3d 1325, 1330 (Fed. Cir. 2008). A fact is "material" only if its resolution will affect the outcome of the lawsuit. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248, 106 S. Ct. 2505, 91 L. Ed. 2d 202 (1986); *Daugherty v. Sajar Plastics, Inc.*, 544 F.3d 696, 702 (6th Cir. 2008). Determination of whether a factual issue is "genuine" requires consideration of the applicable evidentiary standards. Thus, in most civil cases, the Court will decide "whether reasonable jurors could find by a preponderance of the evidence that the [non-moving party] is entitled to a verdict." *Anderson*, 477 U.S. at 252.

Upon filing a motion for summary judgment, the moving party has the initial burden of establishing that there are no genuine issues of material fact as to an essential element of the non-moving party's claim. *Street v. J.C. Bradford & Co.*, 886 F.2d 1472, 1479-80 & n.12

(6th Cir. 1989); *Moldowan v. City of Warren*, 570 F.3d 698, 719 (6th Cir. 2009). The moving party, however, is not required to file affidavits or other similar materials negating a claim on which its opponent bears the burden of proof, so long as the moving party relies upon the absence of the essential element in the pleadings, depositions, answers to interrogatories, and admissions on file. *Celotex Corp. v. Catrett*, 477 U.S. 317, 106 S. Ct. 2548, 91 L. Ed. 2d 265 (1986); *Curto v. Harper Woods*, 954 F.2d 1237, 1241 (6th Cir. 1992) (quoting *Celotex*, 477 U.S. at 322); *Ocean Innovations, Inc. v. Quarterberth, Inc.*, No. 1:03-CV-0913, 2009 U.S. Dist. LEXIS 54108, at *8-9 (N.D. Ohio June 26, 2009) (citing *Celotex*, 477 U.S. at 322).

In response, if the moving party establishes the absence of a genuine issue of material fact, to defeat summary judgment, the non-moving party "may not rely merely on allegations or denials in its own pleading; rather, its response must — by affidavits or as otherwise provided in this rule — set out specific facts showing a genuine issue for trial." Fed. R. Civ. P. 56(e)(2); *see also Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586-87, 106 S. Ct. 1348, 89 L. Ed. 2d 538 (1986). In this regard, "Rule 56 does not impose upon the district court a duty to sift through the record in search of evidence to support a party's opposition to summary judgment"; rather, "Rule 56 allocates that duty to the opponent of the motion, who is required to point out the evidence, albeit evidence that is already in the record, that creates an issue of fact." *Williamson v. Aetna Life Ins. Co.*, 481 F.3d 369, 379-80 (6th Cir. 2007) (citation omitted). Moreover, the non-moving party must

show more than a scintilla of evidence to overcome summary judgment; it is not enough for the non-moving party to show that there is some metaphysical doubt as to material facts. *Matsushita Elec. Indus. Co.*, 475 U.S. at 586-87; *see also Vita-Mix*, ___ F .3d ___, 2009 U.S. App. LEXIS 20622, 2009 WL 2950226 at *3; *Barr v. Lafon*, 538 F.3d 554, 574 (6th Cir. 2008).

Accordingly, the ultimate inquiry is whether the record, as a whole, and upon viewing it in the light most favorable to the non-moving party, could lead a rational trier of fact to find in favor of the non-moving party. *Matsushita Elec. Indus. Co.*, 475 U.S. at 586-87; *see also Anderson*, 477 U.S. at 252 ("The judge's inquiry, therefore, unavoidably asks whether reasonable jurors could find by a preponderance of the evidence that the [non-moving party] is entitled to a verdict — whether there is [evidence] upon which a jury can properly proceed to find a verdict for the party producing it, upon whom the onus of proof is imposed.") (emphasis in original) (internal quotations omitted); *Amgen, Inc. v. F. Hoffman -LA Roche Ltd.*, 580 F.3d 1340, 2009 U.S. App. LEXIS 20409, 2009 WL 2928763, *7 (Fed. Cir. Sept. 15, 2009).

In the context of a patent infringement case, "whether a particular device infringes a properly construed claim[] is a question of fact." *Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp.*, 149 F.3d 1309, 1315 (Fed. Cir. 1998). Consequently, summary judgment of noninfringement only is appropriate where "no reasonable fact finder could find infringement." *Id.* As

stated by the Federal Circuit: "We affirm a district court's grant of summary judgment of non-infringement only if, after viewing the alleged facts in the light most favorable to the non-movant, there is no genuine issue as to whether the accused device is encompassed by the claims." *Wavetronix LLC v. EIS Electronic Integrated Sys.*, 573 F.3d 1343, 1354 (Fed. Cir. 2009) (quoting *Combined Sys., Inc. v. Def. Tech. Corp. of Am.*, 350 F.3d 1207, 1210 (Fed.Cir.2003) (citation omitted)).

B. STANDARDS FOR PATENT INFRINGEMENT

"Infringement analysis involves a two-step process: the court first determines the meaning of disputed claim terms and then compares the accused device to the claims as construed." *Wavetronix LLC*, 573 F.3d at 1354 (citing *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed.Cir.1995), *aff'd*, 517 U.S. 370, 116 S. Ct. 1384, 134 L. Ed. 2d 577 (1996); *see also Middleton, Inc. v. Minn. Mining & Mfg. Co.*, 311 F.3d 1384, 1387 (Fed.Cir.2002)).

Claim construction is a matter of law. *Markman*, 52 F.3d at 976. In this case, the Court has already construed the limitations of the claim at issue in an extensive *Markman* Opinion. Therefore, the first step of the infringement analysis is theoretically complete. The existence of the *Markman* Opinion does not preclude the Court from re-visiting its constructions as its understanding of the technology at issue is informed by the infringement analysis, however. *See Jang v. Boston*

Scientific Corp., 532 F.3d 1330, 1337 (Fed. Cir. 2008) ("Indeed, a better understanding of the context of the claim construction as a case proceeds through an infringement determination can appropriately lead a district court to change its initial claim construction."); *Kenall Mfg. Co. v. Genlyte Thomas Group LLC*, 439 F. Supp. 2d 854, 862 (N.D. Ill. 2006) (choosing to "clarify and elaborate on" initial claim construction "so as to eliminate further confusion-or manipulation-of its meaning by the parties.").

The second step in the infringement analysis — comparison of the claims to the accused device — is a question of fact. *Ethicon Endo-Surgery, Inc.*, 149 F.3d at 1315. The "all elements rule" applies to the process of comparing the claims to the accused device: "an accused product or process is not infringing unless it contains each limitation of the claim, either literally or by an equivalent." *PSN Illinois, LLC v. Ivoclar Vivadent, Inc.*, 525 F.3d 1159, 1168 (Fed. Cir. 2008) (quoting *Freedrnan Seating Co. v. Am. Seating Co.*, 420 F.3d 1350, 1358 (Fed.Cir. 2005)).

In general, a patent may be infringed literally or under the doctrine of equivalents. Literal infringement occurs when each limitation or element of a claim of the patent at issue is present in the accused device. *Id.; see also Cole v. Kimberly-Clark Corp.*, 102 F.3d 524, 532 (Fed. Cir. 1996). Even if each limitation or element of a claim is not literally met by the accused device, infringement may be found under the doctrine of equivalents if the differences are insubstantial. *See Boehringer Ingelheim Vetmedica, Inc. v. Schering-*

Plough Corp., 320 F.3d 1339, 1351 (Fed. Cir. 2003). "Infringement analysis under the doctrine of equivalents proceeds element-by-element; a generalized showing of equivalency between the claim as a whole and the allegedly infringing product or process is not sufficient to show infringement." *Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1296 (Fed. Cir. 2009) (citing *Warner-Jenkinson Co. v. Hilton-Davis Chemical Co.*, 520 U.S. 17, 29, 117 S. Ct. 1040, 137 L. Ed. 2d 146 (1997), stating that "the doctrine of equivalents must be applied to individual elements of the claim, not to the invention as a whole"); *Paice LLC v. Toyota Motor Corp.*, 504 F.3d 1293, 1305 (Fed. Cir. 2007) (citing *Texas Instruments, Inc. v. Cypress Semiconductor Corp.*, 90 F.3d 1558, 1567 (Fed. Cir. 1996)) ("[G]eneralized testimony as to the overall similarity between the claims and the accused infringer's product or process will not suffice.").

One way to determine whether each element in the patent has an equivalent in the accused device is to analyze whether the element in the accused device "performs substantially the same function in substantially the same way to obtain the same result" as the corresponding claim limitation in the patent. *Abbott Labs.*, 566 F.3d at 1296. This is known as the "function-way-result" or "triple identity" test. *Id.* To prove infringement under the function-way-result test, the plaintiff must produce "*evidence* to establish *what* the function, way, result of *both* the claimed device and the accused device are, and *why* those functions, ways and results are substantially the same[.]" *Malta v. Schulmerich Carillons, Inc.*, 952 F.2d 1320, 1327 n.5 (Fed. Cir. 1991) (emphasis in original).

The function-way-result test is not the only method of proving infringement under the doctrine of equivalents, however, because "[d]ifferent linguistic frameworks may be more suitable to different cases[.]" *Warner-Jenkinson*, 520 U.S. at 40. "Equivalency may also be proven where the differences between the invention as claimed and the accused product or process are insubstantial." *Abbott Labs.*, 566 F.3d at 1297 (citing *Hilton Davis Chem. Co. v. Warner-Jenkinson Co.*, 62 F.3d 1512, 1517-18 (Fed.Cir.1995) (*en Banc*), *rev'd* on other grounds, 520 U.S. 17, 117 S. Ct. 1040, 137 L. Ed. 2d 146 (1997)). This is known as the insubstantial differences test. *Id.*

C. ANALYSIS OF THE DISPUTED ASPECTS OF CLAIM 7

Baran contends that the BioPince contains each of the three limitations of claim 7 of the '797 Patent that the Court construed in its *Markman* Opinion. MDTech moves for summary judgment of noninfringement on the grounds that the BioPince does not contain any of these limitations as a matter of law. The Court will now address each of the disputed limitations in turn.

1. The Cannula Mount Limitation: "a cannula mount affixing the cannula to the guide"

The first disputed term of claim 7 of the '797 Patent is "a cannula mount affixing the cannula to the guide."

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a. The Court's Construction of the Cannula Mount Limitation

The Court construed "a cannula mount affixing the cannula to the guide" as "a structure or support which attaches or connects the cannula to the guide." (*Markman* Opinion at 49-50.) In so holding, the Court rejected Baran's argument that the "cannula mount" can be "anything." Specifically, the Court explained as follows:

> The Court agrees with MDTech that, based on the specification, prosecution history, and dictionary definition, "cannula mount" cannot simply mean "anything." Rather, the Court concludes that this language contemplates and, thus, claims a piece or structure which is independent from the structures which are the guide and the cannula, and serves the function of connecting the two other structures. Thus, the Court construes "a cannula mount affixing the cannula to the guide" to mean "a structure or support which attaches or connects the cannula to the guide."

(*Markman* Opinion at 19-20.)

The Court notes several additional aspects of its construction of this limitation worthy of consideration for purposes of resolving this motion for summary judgment. First, the Court noted in the *Markman*

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Opinion that MDTech's counsel agreed at the *Markman* hearing that the word "support" could be substituted for the word "structure" in its proposed construction ("a support which attaches the cutting cannula to the guide in a secured manner"). (*Markman* Opinion at 17.) Second, the issue of whether a dab of adhesive alone satisfies this limitation was foreshadowed by the arguments at the *Markman* stage. In opposing Baran's proposed construction that the cannula mount could be "anything" that joins the cannula and the guide together, MDTech specifically noted that "'anything' could include glue, velcro, or other materials that can attach or affix components and that are not themselves structures." (*Id.* at 18.) Third, in spite of the fact that the issue of whether adhesive is a cannula mount was at least presaged at the *Markman* hearing, MDTech did not request, nor did the Court adopt, a negative construction that would unequivocally preclude adhesive from satisfying the cannula mount limitation. Fourth, the Court noted in the *Markman* Opinion that the cannula mount limitation of claim 7 of the '797 Patent was amended from "a guide having means affixing the cannula thereto" to its present form ("a cannula mount affixing the cannula to the guide"). (*Id.* at 19.) In the absence of an alternative explanation for this amendment, the Court concluded that the prosecution history favored a construction requiring an independent entity — *i.e.*, a "structure or support" — as the cannula mount. Finally, although the Court agreed with MDTech that a cannula mount cannot be "anything" that joins the cannula and the guide together, and required a "structure or support" "independent from the

structures which are the cannula and the guide," it did not impose the condition that the "independent" cannula mount be "pre-formed."

b. Infringement Analysis

The parties agree that the "cannula mount" in the BioPince consists entirely and exclusively of a dab of "adhesive," and, more specifically, "epoxy." It is undisputed, moreover, that the epoxy used in the BioPince affixes the cannula to the guide. For purposes of summary judgment, the debate is whether that epoxy is an independent "structure or support" such that it reads on the "cannula mount" limitation of the '797 Patent, either literally or under the doctrine of equivalents. Specifically, the issue is whether the epoxy that affixes the cannula to the guide is a structure or support independent from the structures which are the cannula and the guide. In other words, would substituting "epoxy" for "cannula mount" change the meaning of this particular limitation of claim 7 of the '797 Patent? Based on the parties' submissions, the Court finds that MDTech is not entitled to summary judgment on this issue because there is a material issue of fact with respect to whether the dab of epoxy is, in and of itself, a "support or structure" independent from the structures which are the cannula and the guide.

MDTech argues that the BioPince does not have a "cannula mount" because adhesive, in and of itself, cannot be considered a "structure" or "support." To support its argument, MDTech quotes the Court's conclusion that this limitation of the '797 Patent "contemplates,

and, thus, claims a piece or structure which is independent from the structures which are the guide and the cannula, and serves the function of connecting the two other structures" (*Markman* Opinion at 19). MDTech argues that "adhesive has no independent form, uniform geometry, shape, surface area, coverage, or strength as the adhesive will simply flow over the V-shaped trough where the Cannula rests . . . [i]t cannot be independently fabricated." (Opp'n Br. at 26.) MDTech further argues that the teachings of the '797 Patent preclude interpreting the "cannula mount" as a dab of adhesive because the specifications of the patent teach a cannula mount that "can be adhesively bonded to a bore of the guide . . ." (*Id*. at 27.) Consequently, MDTech contends that, if the cannula mount may be entirely made of adhesive, then the '797 Patent teaches adhesive bonded to adhesive. (*Id.*) In sum, MDTech contends that the specifications of the '797 Patent teach a *pre-formed*, independent structure playing the role of the cannula mount while, in the BioPince, adhesive affixes the cannula to the guide and there is no pre-formed, independent "structure" to satisfy the "cannula guide" limitation as construed by the Court.

In addition, MDTech's expert, Dr. Rashidi, testified that a dab of epoxy could never be an independent structure or support because it is merely an agent that "bonds" or "welds" the stainless steel cannula and the plastic guide together. (*See* MSJ at 26.) In other words, Rashidi asserts that the BioPince "simply does not have

[a cannula mount], but instead relies on a physiochemical reaction to bond or weld the cannula to the Guide." (*Id.* at 28.) He states that:

> the adhesive connects the cannula to the rear guide with a mechanism of adhesion and adhesion has a very well defined definition. And as I said, there is a physiochemical reaction and interaction among three items, one is solid A, which is the plastic [guide], solid B, which is the stainless steel [carinula], and adhesive agent and the way the adhesion works is creates two boundaries, one is between adhesive and solid A and between adhesive and solid B and they put it all together and that mechanism is very different than having a support structure to connect two pieces together.

(Rashidi Dep. at 160.) Rashidi's fundamental conclusion is that the epoxy cannot be a "structure or support" because it is a bonding agent without an independent structure unto itself.

In response to MDTech's arguments concerning this term, Baran first notes that MDTech argued at the *Markman* hearing that the adhesive connecting the cannula to the guide is not a "structure," but did not argue that the adhesive is not a "support." Accordingly, Baran's first argument is that, since the Court defined a "cannula mount" as a "structure *or support*," and MDTech does not dispute that the adhesive in the

BioPince acts as a *support*, there is literal infringement. Further, Baran argues that, although the Court stated that the "cannula mount" is a "piece or structure . . . independent from . . . the guide or cannula," the Court did not impose the limitations MDTech raises, *i.e.*, "independent form, uniform geometry, shape, surface area, coverage, or strength." In fact, notes Baran, MDTech did not propose such requirements in its proposed constructions at the *Markman* stage, despite the fact that, at the time, MDTech knew Baran considered the adhesive to be the cannula mount.

In sum, Baran argues that whether the adhesive is a structure or a support is a material issue of fact. He asserts that, for example, certain adhesives — such as the epoxy used in the BioPince[13] — are polymer structures in their hardened form. Accordingly, he argues that whether epoxy in its hardened state is a "structure" or "support" for purposes of the '797 Patent is a jury question.

In response to MDTech expert, Dr. Rashidi, Baran notes that the American Heritage Dictionary defines "epoxy" as "any of various usually thermosetting resins capable of forming tight cross-linked polymer structures characterized by toughness, strong adhesion, and low shrinkage, used especially in surface coatings and adhesives." (Opp'n Br. at 20 (emphasis added).) Baran's expert, Dr. Hagga, similarly testified that a hardened

13. It is undisputed that the type of adhesive used in the BioPince to affix the cannula to the guide is an epoxy. (*See* Opp'n Br. at 20.)

polymer such as epoxy is a structure. (*Id.*) He noted that the determinative factor with respect to whether something is a "structure" should not be its initial state of matter (*i.e.*, solid, liquid, or gas) because, if that were the case, the injection molded plastic used to fabricate, *e.g.*, the guide, would not be a "structure." (Doc. 172-7, Haaga Dep. at 122.)

This evidence indicates that the parties, ultimately, do not dispute that the dab of epoxy has a physical presence and plays a role in establishing the connection between the cannula and the guide. It does not resolve the question of whether the epoxy is a structure or support independent of the cannula and guide, however.

The Court finds that Baran has raised a genuine issue of material fact with respect to whether the dab of hardened adhesive that connects the cannula to the guide is the "cannula mount" as the term was construed by the Court. MDTech's description of a dab of adhesive as an amorphous substance whose ultimate physical characteristics depend entirely upon its surroundings is compelling. In addition, MDTech's argument that the specifications do not contemplate a structure consisting of adhesive attached to adhesive is persuasive. But Baran's position has merit as well. Epoxy, like plastic, begins as a liquid but becomes a solid. It performs its function in its solid state. It forms a solid (admittedly, via the principles of adhesion Rashidi alludes to) that surrounds the cannula and the guide, affixing them to it, and, consequently, to each other. Characterizing this solid dab of epoxy as a "structure or support" is not entirely unreasonable. Furthermore, characterized as

such, the concept of adhesive attached to adhesive is not so far-fetched. Accordingly, although this is a close question, especially given that, considered in their entirety, the specifications do not appear to contemplate Baran's interpretation, the Court cannot conclude that no reasonable juror could find that the dab of epoxy is "a structure or support which attaches or connects the cannula to the guide." (*Markman* Opinion at 49-50.) Summary judgment of noninfringement is, thus, not appropriate with respect to this limitation of claim 7. [14]

2. The Charging Member Limitation: "a manually operable charging member for moving the guide to the charged position against the urging of the coil spring"

The second disputed term of claim 7 of the '797 Patent is "a manually operable charging member for moving the guide to the charged position against the urging of the coil spring."

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14. The Court notes that it could conceivably grant summary judgment of noninfringement by adding a negative limitation to its construction of the cannula mount claim — *i.e.*, by finding that a cannula mount cannot be a dab of adhesive based on the fact that, when the specifications mention adhesive, it is in a manner inconsistent with Baran's argument in support of that conclusion. *See, e.g., Kenall Mfg. Co.*, 439 F. Supp. 2d at 862 (choosing to "clarify and elaborate on" initial claim construction "so as to eliminate further confusion-or manipulation-of its meaning by the parties.") The Court concludes that this approach is not appropriate with respect to this claim, however, in light of the fact that (1) MDTech did not

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Appendix E

a. The Court's Construction of the Charging Member Limitation

The Court construed "a manually operable charging member for moving the guide to the charged position against the urging of the coil spring" as "*a manually operable charging member that is used to create a charge or stored energy, the charging member configured to move the guide to the charged position against the urging of the coil spring.*" (*Markman* Opinion at 59-60.) In so construing this limitation, the Court specifically chose not to adopt Baran's proposed construction in which a "mechanism" would be synonymous with a "member." (*Id.* at 22.) Instead, the Court found that "the term 'mechanism' is inconsistent with the common and ordinary meaning of 'member' to someone skilled in the art, as well as with what is disclosed in the patent specification." (*Id.*) The Court described the ordinary meaning of the terms "mechanism" and "member" as follows:

> Indeed, "mechanism" is defined as "1a: a piece of machinery: a structure of working parts functioning together to produce an effect." Webster's Third New International Dictionary

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request such a construction at the *Markman* stage or in the context of this motion for summary judgment; (2) no significant new and relevant evidence has come to light; and (3) the Court conducted a detailed analysis and articulated a very specific and refined construction of the limitation that will provide the finder of fact with clear guidance in resolving this question.

> 1401(1993); *see also* Merriam-Webster Online Dictionary, *www. m-w. com* (defining "mechanism" as "1:a: a piece of machinery."). On the other hand, "member" is defined as "4: a constituent part of a whole, as . . . d(2): an essential part of a framed structure, a machine, or a device." Webster's Third New International Dictionary 1408 (1993); *see also* Mirriam-Webster Online Dictionary, *www. m-w. com*, (defining "member as "4: a part of a whole."). A mechanism, therefore, is not commonly understood to be simply a single part that has multiple components; a mechanism itself has multiple parts. Nor can "member" and "mechanism" be treated as synonymous, as Plaintiff seemingly attempts to do.

(*Id.* at 22-23.) In addition, the Court found that the specifications did not support Baran's argument that "member" and "mechanism" are synonymous.

> Indeed, as MDTech argues, the specification actually counsels that, in defining "member," the Court should err on the side of simplicity rather than on the side of complexity. The only references to "mechanism" in the specification relate to prior art, are accompanied by the term "complicated," and are the very types of elements that Baran asserts he was attempting to remedy by making his invention more simple. Given that, and absent any other

> source to expand the meaning of "member" as it is used in claim 7, the Court cannot define "member" as including the alternate term "mechanism."

(*Id.* at 23.) Ultimately, the Court did circumscribe the scope of its construction, however, explaining as follows:

> The Court notes, however, that, in finding that "member" does not encompass "mechanism," it only determines what "member" is *not*; it does not determine how it should be defined. For their part, the parties offer little guidance and, indeed, do not even attempt to define member. [15] Given that the parties do not seek to define "member," and that their sole dispute over this term is whether it could be defined to include "mechanism," the Court sees no need to further define this term. Accordingly, the Court construes "a manually operable charging member for moving the guide to the charged position against the urging of the coil spring" pursuant to Plaintiff's proposed construction, absent the

15. As noted at the *Markman* hearing:

THE COURT: But, you don't even seek to define member, really, other than — what you seek to define is manually.

MS. THOMPSON (counsel for MDTech): No, I seek to define member only insofar as to exclude the expansion that Plaintiffs put on it.

(Tr. at 88.)

> term "mechanism," as follows: "*a manually operable charging member that is used to create a charge or stored energy, the charging member configured to move the guide to the charged position against the urging of the coil spring.*"

(*Markman* Opinion at 25-26.) On summary judgment, the question is now whether the BioPince "mechanism," which undisputedly includes a "member," may, as a matter of law, infringe the "charging member limitation" of the '797 Patent, which teaches a "member configured to move the guide to the charged position against the urging of the coil spring."

b. Infringement Analysis: The BioPince Does Not Literally Infringe the Charging Member Limitation of Claim 7 of the '797 Patent

Again, "literal infringement occurs when 'every limitation recited in the claim is found in the accused device[.]'" *Bass Pro Trademarks, L.L.C. v. Cabela's, Inc..*, 485 F.3d 1364, 1369 (Fed. Cir. 2007) (quoting *Engel Indus., Inc. v. Lockformer Co.*, 96 F.3d 1398, 1405 (Fed. Cir. 1996)). Accordingly, in order to prove that the BioPince literally infringes the charging member limitation of the '797 Patent, Baran must demonstrate that the BioPince has (as the limitation was construed by the Court), "*a manually operable charging member that is used to create a charge or stored energy, the charging member configured to move the guide to the*

charged position against the urging of the coil spring." (*Markman* Opinion at 59-60 (emphasis in original).)

MDTech concedes that a "mechanism" is made up of component "members." It also concedes that a "member" need not be a single component structure — it could be more than one component moving in unison, as long as the structure does not constitute a group of independent parts mechanized to work together. (*Markman* Hrg. 89.) In addition, Baran identifies the long blue or green "crank arm" as the "member" of the BioPince that reads on the charging member limitation of the '797 Patent. MDTech does not dispute that the "crank arm" is "manually operable," and is a component member of the slider-crank mechanism. Accordingly, the issue is whether the crank arm, considered independently of the remaining component members of the slider-crank mechanism, reads on the charging member limitation in the '797 Patent.

MDTech argues that the Court already determined that a mechanism is not a member, nor is it equivalent to a member. MDTech's central contention is that the BioPince's slider-crank mechanism charges the spring by virtue of the *concerted* action of three component members of the mechanism as a whole, not because of the action of any single component member or even the in-unison operation of multiple component members bonded together. According to MDTech, a mechanism must be treated as an entity unto itself; dividing it into its component parts (*i.e.*, "members") undermines its essential nature. Therefore, MDTech fundamentally

disagrees with the proposition that the crank arm (or, for that matter, any other member of the slide-crank mechanism) could read on the charging member limitation of the '797 Patent. MDTech asserts that the theoretical distinction between a member and a mechanism is readily apparent in the difference between the way the BioPince charges the spring and the '797 Patent's teachings for charging the spring. Whereas the '797 Patent teaches a single member working directly against the urging of the spring to compress it — *without* the benefit of any mechanical advantage, the BioPince uses a slider-crank mechanism consisting of a lever (the "crank arm"), which moves the "crank arm fixer," which moves the "slider link" to compress the spring with a significant mechanical advantage.[16]

For his part, Baran points out that, although the Court stated in the *Markman* Opinion that "'member' does not encompass 'mechanism,'" it did *not* address the converse — whether a mechanism could include a member, Further, Baran notes that the Court expressly stated that, because the parties did not ask for a definition of "member," its construction of the charging member limitation was not intended to define "member,"

16. The experts agree that there is a mechanical advantage in using the BioPince's slider-crank mechanism, and no mechanical advantage in the method of compressing the spring claimed by the '797 Patent. Dr. Rashidi testified at length regarding the scientific principles underlying the BioPince's slider-crank mechanism and the significant benefits of using that particular charging mechanism in the BioPince. The Court finds Dr. Rashidi's testimony on this point credible and unrebutted.

except to conclude that it was not synonymous with "mechanism." Baran also contends that MDTech is now attempting to read into the Court's construction a limitation that the member must act "directly" against the guide, a requirement that does not appear in the Court's *Markman* Opinion. Accordingly, Baran argues that the crank arm of the BioPince satisfies the charging member limitation of the '797 Patent because it is: (1) manually operable; (2) a member; (3) used to create a charge; and (4) configured to move the guide to the charged position against the urging of the spring (albeit in conjunction with the other members of the slider-crank mechanism).

In reply, MDTech contends that Baran's argument is inconsistent with the Court's construction of "member" to exclude a "mechanism." MDTech argues that the Court's conclusion that "member" is not synonymous with "mechanism" would be meaningless if Baran were allowed to compare a single component of the slider-crank mechanism to the charging member in the '797 Patent for purposes of proving infringement. As stated by MDTech:

> Every manually operated mechanism necessarily includes at least one member. According to Baran's interpretation, every use of the word "member" would subsume the term "mechanism," because, in Baran's world, one cannot distinguish a mechanism from a member.

(Reply Br. at 20.) In addition, MDTech notes that the requirement that the charging member operates *directly* on the guide is "inherent" in the Court's construction, which requires the manually operable charging member to be "configured to move the guide." (Reply Br. at 19 (emphasis added).) MDTech notes that the crank arm — Baran's proposed "charging member" in the BioPince — is not configured to move the guide because it is separated from the guide by two other component members of the slider-crank mechanism. In other words, MDTech asserts that under no circumstances is the crank arm "configured" to move the guide because the crank arm itself is not adjacent to the guide at any point and is multiple components removed from the guide within the slider-crank mechanism.

The Court finds MDTech's arguments with respect to the charging member limitation persuasive, and, accordingly finds that MDTech is entitled to summary judgment of noninfringement. *See Bai v. L & L Wings, Inc.*, 160 F.3d 1350, 1353 (Fed. Cir. 1998) (noting that summary judgment of noninfringement is required if just one limitation is not present). There is no genuine issue of material fact that the charging member limitation of claim 7 of the '797 Patent is not present in the BioPince.

First, the Court's *Markman* Opinion recognizes the fundamental distinction between a mechanism and a member. The Court stated that a member is a "single part," while "a mechanism itself has multiple parts."

(*Markman* Opinion at 23.) The Court also specifically noted that the specifications of the '797 Patent itself distinguished members and mechanisms by referring pejoratively to prior art using "complicated biasing mechanisms," "upon which the patent sought to improve" by using a simple charging *member*. (*Id.* at 21.) Therefore, both Baran and the Court have previously recognized that the terms "member" and "mechanism" express fundamentally different concepts. In addition, both Baran and the Court have already concluded that Baran's stated purpose in designing his biopsy instrument was to improve on prior art by *simplifying* the device used to compress the spring.

By distinguishing these terms and refusing to treat them as synonymous, the Court implicitly determined that each is an entity unto itself, with independent validity. [17] Baran's argument requires the Court to dissect the slider-crank mechanism and treat each component "member" of the mechanism as functioning individually (*i.e.*, separate and apart from the other components), despite the fact that the Court discussed the definition of "mechanism" in the *Markman* Order and specifically noted that a mechanism is "a structure of working parts functioning together to produce an

17. An analogy may be useful in illustrating this concept. Musical notation uses notes and chords. A note is an essential 19. The Court does *not*, as Baran fears, construe the concept of "configured to move the guide" to only cover the preferred embodiment of the '797 Patent. It simply concludes that a component that is several mechanical steps away from the movement of the guide, where those interim steps operate as they do within the BioPince, does not satisfy that limitation.

effect." (*Markman* Opinion at 22-23 (quoting Webster's Third New International Dictionary 1401 (1993).)

Indeed, whether a member can have multiple components is not a new issue. The Court considered the question of whether individual components of a mechanism read on a member during the *Markman* stage of this litigation. The Court described MDTech's position as follows:

> As an initial matter, the defendant does not seek to limit the term member to a *single component* structure. At the hearing, counsel for MDTech said: "I'm not saying it has to be a single part. I mean, if it were two things welded together that moved in unison, I would consider that still a member." (Tr. at 89.) Rather, MDTech simply argues that Plaintiff's effort to expand "member" to include the far more complicated concept of a "mechanism" reaches too broadly, and effectively rewrites the claim.

(*Markman* Opinion at 24.) In the *Markman* Opinion, the Court analyzed *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359 (Fed. Cir. 2002) in connection with this issue. (*Markman* Opinion at 21-23.) In *CCS Fitness*, the Federal Circuit held that a "member" could encompass a multi-component structure. (*Id.* at 21.) As noted in the *Markman* Opinion, the multi-component "member" in *CCS Fitness* was a single structure with multiple components. *See CCS Fitness*, 288 F.3d at 1367. *CCS Fitness* was a patent infringement lawsuit involving elliptical trainers. The "reciprocating member" in the

patent at issue in that case was a straight metal beam connecting the pedals to a shaft and crank system. The accused device used a u-shaped structure having multiple components to accomplish the same motion. The components of the u-shaped structure in the accused device were connected such that they moved in unison, as opposed to in a series where the movement or action of one component causes the movement or action of the next. In construing the limitation "reciprocating member," the Federal Circuit found "that the term 'member' denotes a beam-like structure that is "a single unit in a larger whole." It is not limited to a straight-bar structure comprising a single component only." *Id.* In analyzing *CCS Fitness* for purposes of construing the "member" limitation in this case, this Court noted that the Federal Circuit "consistently referred to the beam, lever, or structure [of the patent-in-suit] in the *singular* , i.e., a single structure that has multiple components." (*Markman* Opinion at 22 (emphasis in original).) By comparison, this Court noted, "the term 'mechanism' connotes a group of *independent* parts working together." (*Id.* (emphasis in original).) Accordingly, this Court found that the Federal Circuit's construction of "reciprocating member" in *CCS Fitness* does not require a construction of "charging member" that treats "member" and "mechanism" as synonymous. (*Markman* Opinion at 23.)

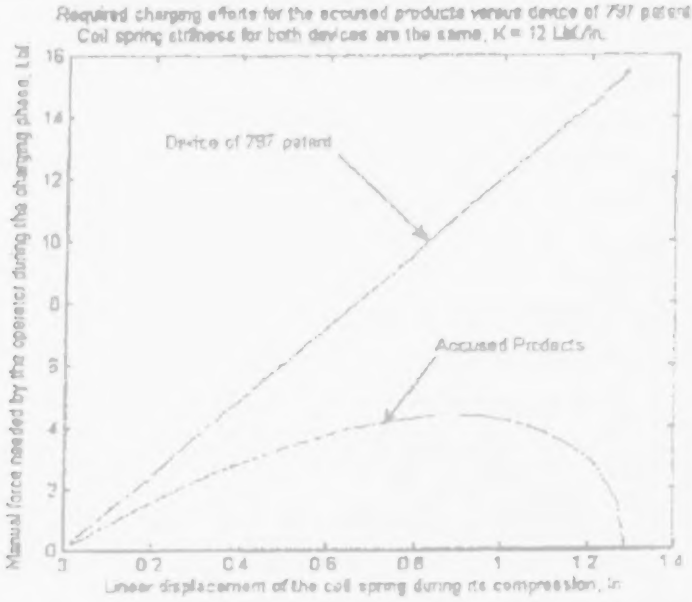
The Court's analysis of *CCS Fitness* in the *Markman* Opinion is particularly useful now that the parties are debating the very issue the Court addressed there. The Court distinguished the "reciprocating member" in *CCS Fitness* from the ordinary meaning of "mechanism" on the grounds that the multi-component

reciprocating member there was a single, unified structure that operated and moved in unison. (*Markman* Opinion at 22.) In other words, the Court concluded that the "reciprocating member" in the accused elliptical trainer was a "member" despite having multiple components because those components operated as a single, unitary piece of the elliptical trainer. Here, the components of the slider crank mechanism, including the crank aim, do not operate in unison, but in series, such that each component acts upon the next in a chain of events (leading to the compression of the spring). Accordingly, the parties' debate regarding the operation of the member in the '797 Patent and the slider-crank mechanism in the BioPince illustrates the distinction the Court explained in its *Markman* Opinion when discussing *CCS Fitness*. More importantly, the Court's analysis of *CCS Fitness* plainly supports MDTech's position — *i.e.*, that the Court's claim construction precludes a reasonable jury from finding that the crank arm is the "charging member."

Baran's comparison between the charging member in the '797 Patent and the crank arm component, *i.e.*, *member*, of the BioPince's slider-crank mechanism is, thus, inconsistent with the fundamental characteristics of a mechanism described in the Court's *Markman* Opinion. An examination of the mechanical differences between the charging member in the '797 Patent and the slider-crank mechanism in the BioPince provide further support for this distinction between the two structures, moreover. (MSJ at 24.)

As Dr. Rashidi explained, there is a measurable difference between the force necessary to compress the

spring, and the manner in which that force is applied in the BioPince and the patented device. (*Id.* (citing Rashidi Dep. at 185-186).) In the '797 Patent, the force necessary to compress the spring increases as the spring reaches maximum compression. (*Id.*) In contrast, the force necessary to compress the spring via the slider-crank mechanism in the BioPince is always less because the mechanism exhibits a mechanical advantage, and although the force necessary to compress the spring increases with compression to a point, by virtue of the scientific characteristics of a slider-crank mechanism, the necessary compression force then decreases to zero at full compression. (*Id.*) Dr. Rashidi's diagram at right Linear displacement of the coil spring during its compression, provides a succinct graphic illustration of this comparison.



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It is undisputed, moreover, that the slider-crank mechanism changes the *direction* of the force used to charge the BioPince, while the force used to charge the '797 device is applied in the same direction as the compression of the spring. (*Id.* at 25.) This fact is particularly meaningful in light of the discussion above regarding *CCS Fitness*. The slider-crank mechanism can charge the spring using force applied in a direction other than the direction of the compression because the multiple components of the mechanism, acting in a series, change the direction of the force until the last component, the guide, acts against the urging of the spring in the direction of the compression. Again, this illustrates that, unlike the "reciprocating member" in *GCS Fitness*, the component parts of the BioPince's slider-crank mechanism do not act in unison. The BioPince's slider-crank mechanism is a vivid example of the type of mechanism the Court described in the *Markman* Opinion — *i.e.*, independent components working together. (*Markman* Opinion at 22.) Viewed in this light, Baran's argument that the crank arm is the charging member is necessarily inconsistent with the Court's analysis of this limitation in the *Markman* Opinion. [18]

In addition, the Court notes that Baran cannot satisfy the requirement that the member be "configured to move the guide." MDTech explains:

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18. While Baran is correct that this Court did not define what a member was, it most certainly defined what a member *is not*. The Court unequivocally concluded that a member is not a series of independent components that work together to accomplish a function by way of movements that include changes in both direction and force.

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> There is no question that the Crank Arm is not "configured" to move the Guide; its shape or configuration would never allow it to operate on the Guide. Instead, the Crank Arm moves the Connecting Rod (30), which moves the Crank Arm Fixer (34), which moves the Slider Link (35), but it does not, and cannot move the Guide.

(Reply Br. at 19-20.) Thus, as both experts testified, the crank arm only participates in moving the guide by virtue of the concerted, sequential action of the other component members in the slider-crank mechanism, such that each component acts upon the next in a chain of events leading to the compression of the spring. Baran does not deny this reality. Baran argues though that the *crank arm* — the only "manually operable" component member of the slider-crank mechanism — is "configured to move the guide" because the guide cannot move without it — *i.e.*, unless the crank arm is manually operated, the other component parts will not engage. Thus, while Baran concedes that the crank arm never touches the guide, or directly engages it, he asserts that there is a "but for" element to its presence: but for operation of the crank arm, the guide would not move.

Baran's reasoning is inconsistent, however, with his own contention that each component member of the slider-crank mechanism can be analyzed independently for purposes of literal infringement. Baran cannot have it both ways. If the crank arm is "configured to move

the guide," it is only by virtue of the concerted, sequential action of the slider-crank mechanism. Therefore, it is the action of the slider-crank mechanism as a whole that is under consideration, and Baran would have to show that a mechanism reads on a member, a showing the Court's *Markman* Opinion precludes. If, on the other hand, the slider-crank mechanism can be disarticulated into its component members for purposes of the infringement analysis, then the individual action of each component member is what is truly under consideration, not the concerted, sequential action of the mechanism as a whole. Ultimately, the claim construction implies that "configured to move the guide" presupposes that the configuration does not require multiple steps in between the operation of the member and the movement of the guide. Consequently, the crank arm — which is not, by itself, configured to move the guide — does not read on the charging member of the '797 Patent. [19]

Finally, it is worth noting that adopting Baran's argument would lead to untenable results that the Court most assuredly did not intend to countenance by its construction of the charging member limitation. In the context of the type of automated biopsy instruments at issue here, there is a logical fallacy at the heart of

19. The Court does *not*, as Baran fears, construe the concept of "configured to move the guide" to only cover the preferred embodiment of the '797 Patent. It simply concludes that a component that is several mechanical steps away from the movement of the guide, where those interim steps operate as they do within the BioPince, does not satisfy that limitation.

Baran's argument. All automated biopsy instruments include a method of charging the device so that it can be automatically discharged to collect a tissue sample. In every automated biopsy device that uses a linear spring to provide the elastic potential energy for the charge, the invention must include a means for compressing the spring, either directly or indirectly. If Baran's interpretation of the Court's claim construction is correct, then *every* method of compressing the spring would read on the charging member limitation of the '797 Patent. As discussed above, for example, in this case, the crank arm never comes into contact with the spring, but, because it is the "manually operable" component of the mechanism that ultimately compresses the spring, it would read on the '797's charging member limitation under Baran's interpretation of that limitation, no matter how complex the mechanism between the initial "manually operable" component and the guide, and no matter how many interim components make up that mechanism. The Court certainly did not intend to so limit the field of potential improvements to biopsy instruments in its *Markman* Opinion. [20]

Accordingly, MDTech is entitled to summary judgment of noninfringement with respect to Baran's

20. The Court does not find, nor is it necessarily convinced, that the logical fallacy discussed above would be present in every situation in which a patentee attempts to prove infringement by arguing that a "member" reads on a "mechanism." This analysis is limited to the automated biopsy instruments at issue in this case.

claim that the BioPince literally infringes the charging member limitation of claim 7 of the '797 Patent. [21]

3. The Release Means for Retaining Limitation: "a release means for retaining the guide in the charged position"

Although summary judgment of noninfringement is required if even one limitation is not present in the accused device, *see Bai*, 160 F.3d at 1353, the Court will

21. In his Opposition Brief, Baran does not argue that the BioPince infringes the charging member limitation under the doctrine of equivalents. Accordingly, the Court need not analyze this issue. The Court will briefly address the doctrine of corresponding structures in both the reusable embodiment and the single-use embodiment. The parties agree that the BioPince is a single-use automated biopsy instrument. Further, as the Court makes clear in the *Markman* Opinion, there is no meaningful difference between the two embodiments of the '797 Patent with respect to the retaining and releasing limitation. Therefore, for infringement purpose, the distinction between the two embodiments is not meaningful.

The BioPince clearly does not infringe under either the "function, way, result" or "insubstantial differences" tests articulated above for infringement under the doctrine of equivalents. The difference between the slider-crank mechanism and the charging member claimed in the '797 Patent is apparent. Under the function-way-result test, it is undisputed that the BioPince does not perform the function at issue — *i.e.*, charging the spring — in the *same* way as the '797 Patent teaches because it uses a slider-crank mechanism that achieves a significant mechanical advantage in charging the spring.

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complete the analysis of the three disputed terms. The third disputed term of claim 7 of the '797 Patent is "a release means for retaining the guide in the charged position."

a. The Court's Construction of the Release Means for Retaining Limitation

At the *Markman* stage of these proceedings, the parties agreed that this limitation should be construed as a means-plus-function claim limitation in accordance with 35 U.S.C. § 112, ¶ 6. (*Markman* Opinion at 26.) Construction of a means-plus-function claim involves a two-step process. First, the Court must identify the recited function that the "means" performs. *Omega Eng'g, Inc.*, 334 F.3d at 1321. Next, the Court must identify the corresponding structure that performs the recited function. *Id.*

The Court conducted this analysis on the "release means for retaining the guide in the charged position" limitation in the *Markman* Opinion. With respect to the first step, the bone of contention between the parties at the *Markman* hearing was whether the function was both retaining and releasing, or just releasing. The

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Likewise, the significant mechanical advantage the BioPince achieves by virtue of the slider-crank mechanism clearly and substantially distinguishes the BioPince from the biopsy instrument claimed in the '797 Patent under the insubstantial differences test. This is presumably why Baran did not attempt to argue that the BioPince infringes the charging member limitation under the doctrine of equivalents.

Court discussed this issue at length and determined that the function of this element includes *both retaining* the guide in the charged position and releasing the guide from the charged position. The Court articulated the function as follows:

> ["a release means for retaining the guide in the charged position"] is a [m]eans-plus-function claim in which the function is "retaining the guide in the charged position and releasing, or setting free, the guide from the charged position."

(*Markman* Opinion at 50.)

In analyzing step two — the corresponding structures — the Court first described the '797 Patent's explanation of the retaining and releasing functions, with reference to Figures 4A and 8A of the '797 Patent.[22]

> As for the retaining function, the patent provides that, to convert the instrument from the discharged mode to the charged mode, "[t]he safety cap 20 and the spring guide 18 are retracted in this manner until the latching projection 102 on the release lever 22 engages in the annular external shoulder 54 of the spring guide." ('797 patent, col. 7, l. 23-27.) Fig. 4A below shows the release lever 22 and latching projection 102 as they appear in the discharged mode.

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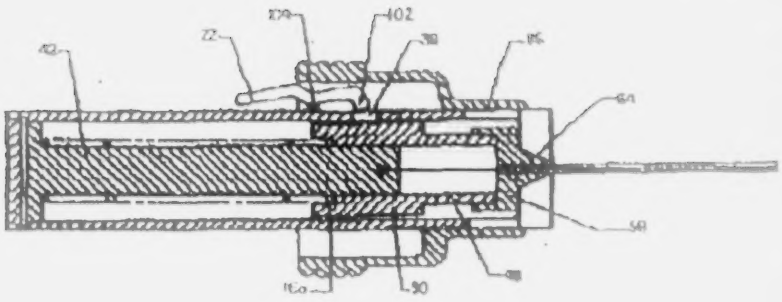


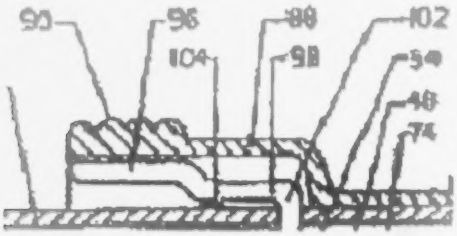
FIG. 4A

Similarly, in the single use embodiment, the patent states that conversion to the charged mode requires that "the latching projection **302** of the release lever **222** engages the external shoulder of the biopsy spring guide **218**." (*Id.*, col. 10, l. 5-7.)

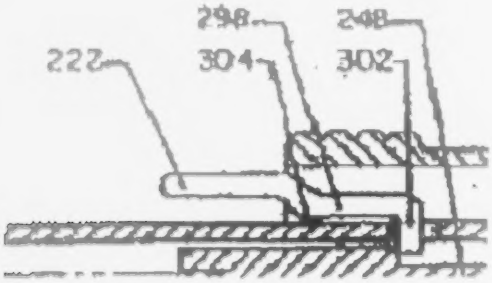
As for the releasing function, the patent explains that "the operator . . . actuates the instrument by depressing the finger rest **96** of the release lever **22**, which is flexibly welded to the outer casing **12** as described hereinabove. Manipulation of the release lever raises the latching projection **102**, disengaging it from the external shoulder **54** of the spring guide **18**." (*Id.*, col. 7, l. 61-67.) The single use embodiment is used "in precisely the same procedure" as the reusable embodiment. (*Id.*, col. 10, l. 14-16.)

In turn, as shown to the right in a portion taken from Fig. 2, "[t]he release lever 22

comprises a finger rest 96 and a mounting section 98 maintained in spaced parallel planes by a connecting web 100 . . . Mounting section 98 is formed with a latching projection 102 at one end of the release lever and is flexibly secured to the outer casing with a spot weld 104." (*Id.*, col. 6, l. 25-32).



Likewise, the single use embodiment contains substantially similar features (with different corresponding numbers), as shown to the right in a portion of the illustration taken from Fig. 8. The description provides that "[t]he mounting section 298 of the release lever 222 is flexibly solvent-bonded to the outer casing at 304. (*Id.*, col. 9, l. 36-37.)



(*Markman* Opinion at 31-33.) The Court then described the structures corresponding to the retaining and releasing function as follows:

> Based on the specification described above, the Court finds that the structures corresponding to the recited functions in this mean-plus-function limitation are the following: . . . for the single use embodiment (Figs. 5-8A), the release lever **222**, including the latching projection **302**, the finger rest (not marked by a reference numeral), and the mounting section **298**, as well as the equivalents thereof.

(*Id.* at 33.) The Court noted that "[a]ll of these structures and their elements are specifically linked to the stated functions of retaining and releasing the spring guide, either in the description of the operation of the instrument or the detailed description of the structures themselves." (*Id.*)

b. Infringement Analysis

MDTech contends that summary judgment of noninfringement is appropriate because, as a matter of law, the BioPince does not infringe the retaining and releasing means-plus-function limitation of the '797 Patent. There is, however, a threshold issue raised by MDTech that must be addressed at the outset.

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i. Whether It Is Appropriate to Analyze Baran's Theory of Infringement Even Though the BioPince Is Not Intended to Be Operated Using the Alternative Method He Proposes

According to MDTech, there is only one legitimate way to "fire" or release the BioPince when it is charged and ready: by pressing the firing button on the end of the plastic casing farthest from the distal end of the needle. Baran disagrees, and his claim that the BioPince infringes the retaining and releasing limitation of the '797 Patent depends entirely on an alternative method of firing/releasing the charged BioPince.

Specifically, Baran asserts that physicians using the BioPince can, and do, release it from the charged position by pulling up on the crank arm to disengage the latching projection from the shoulder in the opening of the crank arm. This procedure is described in greater detail in Dr. Haaga's expert report (with reference to Figures 12 and 13 of Dr. Haaga's expert report):

> As illustrated below in Figures 12 and 13, the BioPince products include a strut or lever stage 60 provided with a release lever 65 that includes a latching projection 70 and a mounting section 75. Applying the claim construction provided by the Court, the latching projection 70 of the release lever 65 is releasably engaged to a shoulder 80 in an opening 85 in the charging member 55, such

> that: i) when the latching projection 70 engages the shoulder 80 of the charging member 55, the guide 40 is retained in its charged position and ii) when the latching projection 70 is disengaged from the shoulder 80 in the opening 85 of the charging member 55 (e.g., by lifting up on the charging member 55 at the site where the strut 60 pivotally connects to the charging member 55), the guide 40 is released or set free from its charged position. Based at least on the foregoing, it is my opinion that this structure (i.e., the release lever 65 that includes a latching projection 70 and a mounting section 75) represents an equivalent structure of the corresponding structures set forth in the Court's claim construction. Accordingly, it is my opinion that the BioPince products satisfy [the releasing and retaining] limitation.

(Haaga Expert Report ¶ 50, Doc. 174-1.) Figures 12 and 13 from Dr. Haaga's Expert Report are reproduced below.[23]

23. The captions to figures 12 and 13 do not appear in Dr. Haaga's report. With one notable exception, the Court has used captions that conform to the numbering in Dr. Haaga's report and the names used throughout this opinion. The exception is the release "lever" 65 in Figure 12. The parties debate whether 65 is a lever or a cantilever. "Release lever" is Haaga's moniker.

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Figures 12 & 13 from Dr. Haaga's Expert Report:

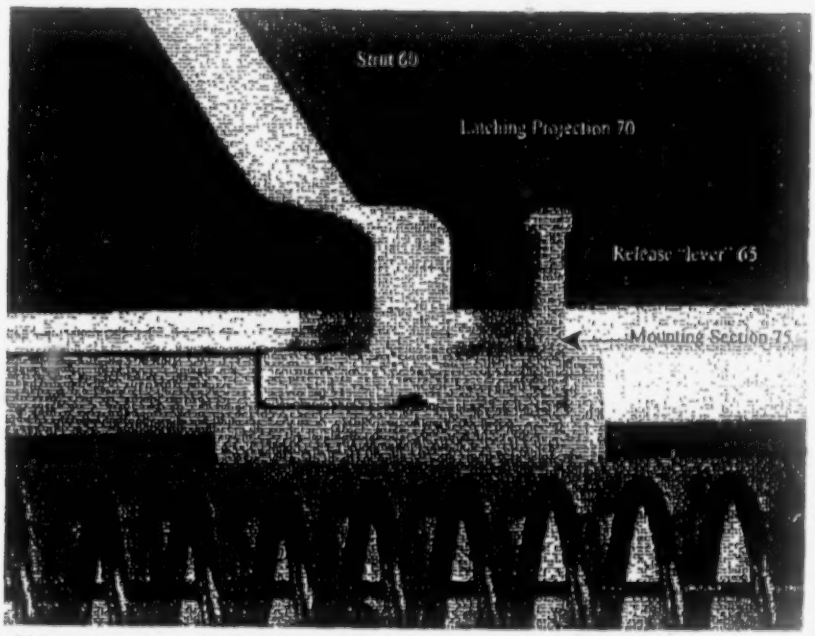

Figure 12 – Haaga's Expert Report (captions added)

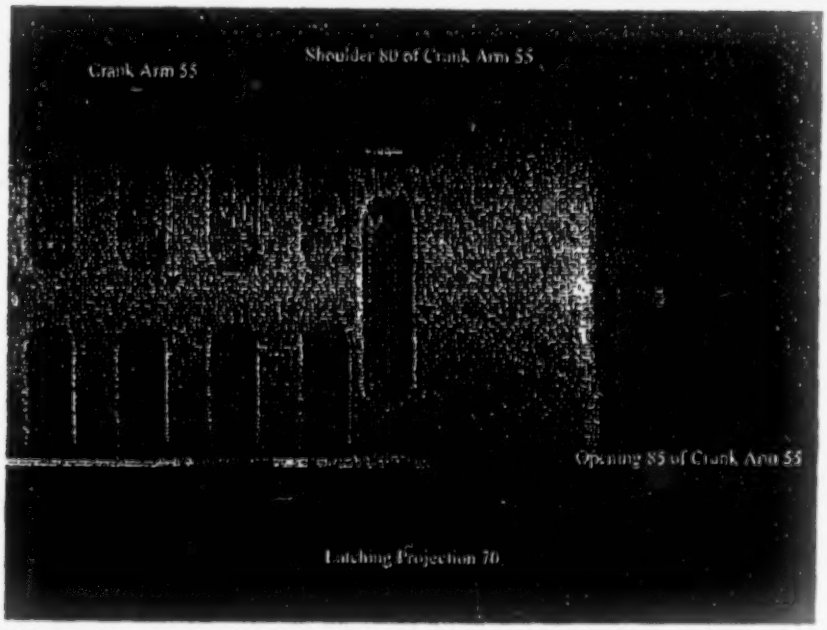

Figure 13 – Haaga's Expert Report (captions added)

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MDTech's first argument with respect to the retaining and releasing limitation is that Baran has not even attempted to argue that the BioPince infringes because all of his arguments relate to an improper, unknown, and dangerous method of discharging the BioPince, *i.e.*, the crank arm discharge method described by Dr. Haaga above.[24] Indeed, Baran does not contend that discharging the BioPince in the manner described in the instructions that accompany the commercially available BioPince — *i.e.*, by pressing the firing button on the end of the plastic casing farthest from the distal end of the needle infringes the releasing and retaining limitation, either literally or under the doctrine of equivalents. Accordingly, the threshold issue is whether a device may infringe a means-plus-function limitation of a patent when the structures of the device which correspond to the function at issue are not intended to perform that function.

MDTech cites *High Tech Med. Instrumentation, Inc. v. New Image Indus., Inc.*, 49 F.3d 1551, 1555-56 (Fed. Cir. 1995), for the principle that "a device does not infringe simply because it is possible to alter it in a way that would satisfy all the limitations of a patent claim." MDTech contends that the Court should evaluate five factors[25] listed in *High Tech* to determine whether an altered device infringes. MDTech argues that the

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24. Dr. Haaga's method will be described as the "crank arm discharge" method in this Memorandum and Order.

25. As stated by MDTech, the five factors in *High Tech* are;

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BioPince does not infringe because there is no evidence that (1) it "intended or anticipated" physicians to use the crank arm to discharge the BioPince; (2) physicians actually operate the BioPince this way; (3) promotional materials or instructions teach or reference this method; or (4) this method serves a functional purpose not already accomplished. Further, MDTech cites *Cross Medical Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1311 (Fed. Cir. 2005) for the proposition that the five-factor *High Tech* test applies "where a claimed limitation is not present until the device is used in an infringing manner — even if the device need not be physically altered in order to infringe." (MSJ at 17.)

Baran relegates MDTech's *High Tech* argument to a footnote, dismissing it as inapposite because the crank arm discharge method is merely one way of using the BioPince as designed. In other words, Baran

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(1) whether the accused infringer "intended or anticipated" that consumers would modify the accused device to operate in an infringing manner;

(2) whether consumers "actually operated" the device in an infringing manner;

(3) whether the device was "designed to be altered or assembled" before operation;

(4) whether the accused infringer's promotional materials refer to an infringing use; and

(5) whether the device "would serve any functional purpose" in its modified configuration "not already accomplished" by other configurations.

distinguishes this case from *High Tech* because the crank arm discharge method does not involve an alteration or modification of the BioPince. Baran does not cite any cases or other authority in support of his position.

There is truth in both parties' arguments. The rule in *High Tech* (*i.e.*, that altering a device so that it is infringing is not sufficient to prove infringement) is well-established. *See Revolution Eyewear, Inc. v. Aspex Eyewear, Inc.*, 563 F.3d 1358, 1369 (Fed. Cir. 2009) ("Revolution points out that a device does not infringe simply because it is possible to alter it in a way that would satisfy all the limitations of a patent claim. . . . This statement is certainly correct.") (omitting citations and quotations). The factual distinction Baran identifies is also valid and important, however. *See id.* at 1370. The crank arm discharge method does not involve a physical alteration of the BioPince, it is merely an alternative way of using the identical device to perform the releasing function, albeit not a recommended one.

The distinction Baran raises between this case and *High Tech* implicates fundamental principles of patent protection. A patent provides the owner with the right to exclude others from "making, using, offering for sale, or selling" the patented invention. 35 U.S.C. § 154(a)(1); 35 U.S.C. § 271(a). "Making" an invention refers to combining all of its parts into an operable whole. *See Deep South Packing Co. v. Laitram Corp.*, 406 U.S. 518, 528, 92 S. Ct. 1700, 32 L. Ed. 2d 273 (1972). The owner of an apparatus patent has the right to exclude others from making the same apparatus. The Federal Circuit has articulated the general rule as follows: "in

determining whether a product claim is infringed, we have held that an accused device may be found to infringe if it is reasonably capable of satisfying the claim limitations, even though it may also be capable of non-infringing modes of operation." *Hilgraeve Corp. v. Symantec Corp.*, 265 F.3d 1336, 1343 (Fed. Cir. 2001) (citing *See Intel Corp. v. United States Int'l Trade Comm'n*, 946 F.2d 821, 832 (Fed.Cir.1991); *Key Pharms., Inc. v. Hercon Labs. Corp.*, 981 F.Supp. 299, 310 (D.Del.1997), *aff'd*, 161 F.3d 709 (Fed.Cir.1998); *HuckMfg. Co. v. Textron, Inc.*, 187 USPQ 388, 408 (E.D.Mich.1975) ("The fact that a device may be used in a manner so as not to infringe the patent is not a defense to a claim of infringement against a manufacturer of the device if it is also reasonably capable of a use that infringes the patent.").

Intel, 946 F.2d 821, cited by *Hilgraeve*, is the case most frequently cited for this general rule. In *Intel*, the patent at issue was for an erasable programmable read-only memory apparatus. *Id.* One of the claim limitations was a "programmable selection means" for choosing between two modes of operation. Although the devices were marketed and sold to operate in *only* the non-infringing mode of operation, they could be operated in either mode as designed and sold. The Federal Circuit found infringement, stating that "the accused device, to be infringing, need only be capable of operating in the [infringing] mode." *Id.* at 832. Evidence of actual use in the infringing mode, moreover, was not required, *id.*, because "making" an infringing apparatus means unifying all of its parts into an operable whole that infringes the patent at issue. How that apparatus is used

is a separate question that implicates the other rights conferred by § 154(a)(1).

The rule in *High Tech* is a corollary to this basic principle. That is, if an accused device must be altered to be considered the "same" product, then it was not infringing as *made*. In fact, the Federal Circuit in *Hilgraeve "cf."*[26] cited *High Tech*, 49 F.3d at 1556 for the general rule, noting in a parenthetical that "an accused device does not infringe if it does not infringe in its normal configuration, even if it may be altered into an infringing configuration under unusual circumstances." *Hilgraeve*, 265 F.3d at 1343; *Intel*, 946 F.2d at 832.[27] Therefore, the five-factor analysis described in *High Tech* is applicable to identify an exception to, or extension

26. The Bluebook defines "*cf.*" as follows: "Cited authority supports a proposition different from the main proposition, butsufficiently analogous to lend support."

27. There is a line of Federal Circuit authority, including recent cases, that, at first blush, appears to contradict *Intel* and *Hilgraeve* by holding that "[i]n order to prove direct infringement, a patentee must either point to specific instances of direct infringement or show that the accused device necessarily infringes the patent in suit." *ACCO Brands, Inc. v. ABA Locks Mfr. Co., Ltd.*, 501 F.3d 1307, 1313 (Fed. Cir. 2007) (citing *Dynacore Holdings Corp. v. U.S. Philips Corp.*, 363 F.3d 1263, 1275-76 (Fed. Cir. 2004)). In *ACCO*, the Federal Circuit stated:

> Here, the parties do not dispute that the accused device can be operated in either of two modes-the infringing Dornfeld method or the noninfringing press-to-lock method. Because the accused device

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> can be used at any given time in a noninfringing manner, the accused device does not necessarily infringe the . . . patent.

Id. Although the facts in *ACCO* appear analogous to the scenario at bar, in which there are two distinct methods of operating the BioPince at issue, the claim at issue in *ACCO* was induced infringement as opposed to infringement by a manufacturer. In fact, the Federal Circuit expressly rejected the defendant's argument under *Hilgraeve*:

> We are further unpersuaded by ACCO's reliance on *Hilgraeve Corp. v. Symantec Corp.*, 265 F.3d 1336 (Fed.Cir.2001), which states that an accused device may be found to infringe a product claim "if it is reasonably capable of satisfying the claim limitations, even though it may also be capable of non-infringing modes of operation." *Id.* at 1343. That broad legal statement does not alter the requirement that ACCO must prove specific instances of direct infringement or that the accused device necessarily infringes the patent in suit, in order to sustain the jury verdict of induced infringement. Hypothetical instances of direct infringement are insufficient to establish vicarious liability or indirect infringement.

ACCO, 501 F.3d at 1313. Although the distinction is only implicit in *ACCO*, in that case, direct infringement arose as an element of induced infringement by a non-manufacturer, not infringement by a manufacturer. The Federal Circuit recently applied the same standard for the direct infringement element in an induced infringement case. *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312 (Fed. Cir. 2009) (citing *ACCO*, 501 F.3d at 1313). The basis of the distinction between

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manufacturers and non-manufacturers is well-articulated in *HuckMfg. Co.*, 187 U.S.P.Q. at 408:

> The fact that a device may be used in a manner so as not to infringe the patent is not a defense to a claim of infringement against a manufacturer of the device if it is also reasonably capable of a use that infringes the patent. In this respect a distinction is drawn between an alleged manufacturing infringer on the one hand and an alleged using infringer on the other hand. For a person who uses a device, infringement is determined by the use to which the invention is actually put, but for a manufacturer, infringement is determined by the use to which the device may reasonably be put or of which it is reasonably capable.

Thus, the Federal Circuit applies the rule stated in *Intel* and *Hilgraeve* — that "an accused device may be found to infringe if it is reasonably capable of satisfying the claim limitations, even though it may also be capable of non-infringing modes of operation" — in cases in which the plaintiff asserts a direct infringement claim against the manufacturer of the accused product; the rule stated in *ACCO* -- that the accused device does not necessarily infringe if it can be used in a noninfringing manner at any given time — applies in cases in which the plaintiff asserts an induced infringement claim against a non-manufacturer of the accused product. Because this case falls into the former category, the rule stated in *Intel* and *Hilgraeve* applies.

Furthermore, the Federal Circuit has distinguished between cases involving a structural limitation in an apparatus claim and a means limitation in an apparatus claim. For example, in *Cross Medical*, 424 F.3d at 1311-12, the Federal Circuit

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of, the general rule; *i.e.*, where the potential alteration or modification was effectively a means of evading the patent rights of another, an accused product may still infringe. Accordingly, because the crank arm method of discharging the BioPince does not involve a physical alteration or modification, *High Tech* is not the applicable authority. *See Revolution Eyewear*, 563 F.3d at 1370 (distinguishing *High Tech* on the grounds that the accused device in that case had to be altered to infringe).

The question, therefore, is whether the BioPince, as designed and sold, is reasonably capable of a use that infringes the patent. *Hilgraeve*, 265 F.3d at 1343. The Federal Circuit very recently addressed a similar issue in *Revolution Eyewear*, 563 F.3d 1358. In *Revolution Eyewear*, the accused device was "a spectacle frame that supports an auxiliary frame, enabling the user to securely fasten a second set of lenses (e.g., sunglass lenses) onto the primary frame (often holding

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analyzed a spinal fixation implant apparatus that included a structural claim requiring the anchor of the device to be in contact with bone. *Id.* Although MDTech cites *Cross Medical* for the proposition that the *High Tech* analysis applies even in the absence of physical alteration of the apparatus, *Cross Medical* did not involve a means-plus-function claim. 424 F.3d at 1311. In contrast, in *Fantasy Sports Properties, Inc. v. Sportsline.com, Inc.*, 287 F.3d 1108, 1117-18 (Fed. Cir. 1998), the Federal Circuit held that a means-plus-function claim was infringed because the apparatus was capable of infringing, regardless of whether it was configured to be used in an infringing manner. *See also R.A.C. C. v. Stun-Tech, Inc.*, 49 U.S.P.Q. 2d 1793 (Fed. Cir. 1998) (unpublished). This case is more analogous to *Fantasy Sports* than *Cross Medical* because the releasing and retaining limitation is a means-plus-function limitation.

prescription lenses)." *Id.* at 1362. One of the claims of the patent at issue relating to the primary frames was "said first magnetic members capable of engaging second magnetic members of an auxiliary spectacle frame." *Id.* at 1369. The Defendant did not dispute that its primary frames included all of the limitations of the claim, but argued that neither its auxiliary frames nor any commercially available auxiliary frames could be used in conjunction with its primary frames in an infringing manner, *i.e.*, by "top-mounting." *Id.* The Plaintiff, however, presented auxiliary frames capable of such use that had been constructed specifically for purposes of the litigation to prove that the accused device was theoretically capable of being used in an infringing manner. *Id.* The Federal Circuit found infringement, reasoning that the case before it was analogous to *Intel Corp.*, and distinguishable from *High Tech.*, because, *inter alia*, it does not involve an alteration of the product as designed or sold.

> Just like the accused product in *Intel*, Revolution's primary frames, although not specifically designed or sold to be used with top-mounting auxiliary frames, are nevertheless capable of being used in that way-the three specially made auxiliary frames proved so. It is irrelevant that Revolution's auxiliary frames, or any other commercially available auxiliary frames, are not actually used in a top-mounting configuration or cannot be so used.

Id. at 1370.

The Court finds that this case is analogous to *Revolution Eyewear* and, accordingly, concludes that summary judgment of noninfringement would not be appropriate if Baran's asserted crank arm discharge method reads on the releasing and retaining limitation of the '797 Patent. The crank arm discharge method does not require physical alteration of the BioPince; it is an alternative method of using the device. Therefore, whether physicians or users of the BioPince actually employ the crank arm discharge method is irrelevant. Indeed, in *Revolution Eyewear*, the plaintiff did not even attempt to demonstrate that anyone actually practiced the infringing use — the plaintiff specially constructed auxiliary frames capable of infringing, and the Court accepted these litigation-specific models as dispositive proof on the issue. 563 F.3d at 1370. Accordingly, if the crank arm discharge method satisfies the limitations of the '797 Patent, then the BioPince is reasonably capable of an infringing use.[28]

ii. Infringement Analysis of Baran's Crank Arm Discharge Method

MDTech argues that, even if the BioPince is capable of being operated using Baran's crank arm discharge

28. Other issues distinguishing this case from *Revolution Eyewear* are best addressed in the context of the infringement analysis. For example: MDTech asserts that the crank arm discharge method does not satisfy the releasing and retaining limitation because there is no connection between the patent claims and the new method; Baran asserts that MDTech is attempting to add a limitation not present in the patent — *i.e.*, a release means appropriate for performing a biopsy.

method, that method does not satisfy the releasing and retaining limitation of the '797 Patent.

a. Standard for Statutory Equivalents — § 112 ¶ 6

The retaining and releasing limitation is a means-plus-function limitation under 35 U.S.C. 112 ¶ 6. "When a patentee chooses to claim a 'means' for performing a specified function, the means clause covers only 'the corresponding structure, material, or acts described in the specification and equivalents thereof.'" *Applied Medical Resources Corp. v. United States Surgical Corp.*, 448 F.3d 1324, 1338 (Fed. Cir. 2006) (Dyk, J., dissenting). The test for infringement of a means-plus-function claim limitation is as follows:

> Literal infringement of a § 112, ¶ 6 limitation requires that the relevant structure in the accused device perform the identical function recited in the claim and be identical or equivalent to the corresponding structure in the specification. . . . Functional identity and either structural identity or equivalence are both necessary.

Odetics, Inc. v. Storage Tech. Corp., 185 F.3d 1259, 1266 (Fed. Cir. 1999) (omitting citations). Proving infringement of a means-plus-function limitation thus involves three steps. The first step is to identify the relevant structure in the accused device. *See Applied Medical*, 448 F.3d at 1333. The second step is to prove

that that structure performs the identical function as the corresponding structure in the specifications of the patent at issue. The third step is to prove that the corresponding structures perform that function in substantially the same way with substantially the same result. *Id.* (citing *Kemco Sales, Inc. v. Control Papers, Co.*, 208 F.3d 1352, 1364 (Fed. Cir. 2000)).[29]

This statutory equivalents test under § 112 ¶ 6 is not the same as the doctrine of equivalents, although the two are closely related. Because the function of the relevant structure in the accused device and the corresponding structure in the specification must be identical, the statutory equivalents test reduces the doctrine of equivalents' function, way, result test to the latter two prongs — the "way" and "result." *See Odetics*, 185 F.3d at 1267. Statutory equivalents exist "if the assertedly equivalent structure performs the claimed function in substantially the same way to achieve substantially the same result as the corresponding structure described in the specification." *Id.* The Federal Circuit explained the difference between statutory equivalence and the doctrine of equivalents in *Odetics*:

> [T]he statutory equivalence analysis, while rooted in similar concepts of insubstantial differences as its doctrine of equivalents

29. Although the parties debate whether MDTech's analysis impermissibly employs a component-by-component approach to structural equivalence, they agree that the standard articulated here is the proper standard for § 112 ¶ 6 equivalence.

> counterpart, is narrower. . . . This is because, under § 112, ¶ 6 equivalence, functional identity is required; thus the equivalence (indeed, identity) of the "function" of the assertedly substitute structure, material, or acts must be first established in order to reach the statutory equivalence analysis. . . . The content of the test for insubstantial differences under § 112, ¶ 6 thus reduces to "way" and "result." That is, the statutory equivalence analysis requires a determination of whether the "way" the assertedly substitute structure performs the claimed function, and the "result" of that performance, is substantially different from the "way" the claimed function is performed by the "corresponding structure, acts, or materials described in the specification," or its "result." Structural equivalence under § 112, ¶ 6 is met only if the differences are insubstantial . . . .

185 F.3d at 1267 (omitting citations).

Further, the statutory equivalents analysis is not a component-by-component comparison of structure and function. *Id.* at 1268. Instead, the relevant overall structure is that which corresponds with the overall function. *Id.* As stated in *Odetics*, a means-plus-function limitation

> is literally met by structure, materials, or acts in the accused device that perform the claimed function in substantially the same way to

> achieve substantially the same result. The individual components, if any, of an overall structure that corresponds to the claimed function are not claim limitations. Rather, the claim limitation is the overall structure corresponding to the claimed function. This is why structures with different numbers of parts may still be equivalent under § 112, ¶ 6, thereby meeting the claim limitation.

Id. As discussed below, the parties debate whether MDTech has violated the rule against component-by-component analysis.

b. The Relevant Structure

Baran asserts that the structure for the release means for retaining limitation in the BioPince consists of (referring to Figures 12 and 13 above) the crank arm 55, with the opening in the crank arm 85, and the shoulder within the opening 80; as well as the release "lever" 65, with the latching projection 70 and the mounting section 75. According to Baran, this crank arm releasing and retaining structure is the structure of the BioPince that corresponds with the releasing and retaining limitation of the '797 Patent.

c. Whether the Crank Arm Releasing and Retaining Structure Identified by Baran Performs the Identical Function as the Disclosed Releasing and Retaining Structure

The Court construed the functions of the "release means for retaining the guide in the charged position" limitation as "retaining the guide in the charged position and releasing, or setting free, the guide from the charged position." (*Markman* Opinion at 30-31.) MDTech argues that the crank arm structure identified by Baran for releasing and retaining the guide does not perform the same functions because (1) it would be reckless to perform a biopsy by releasing the charge in that manner and (2) pulling up on the crank arm does not release the guide, and, therefore, the slot in the crank arm was not retaining the guide either. Both of MDTech's arguments fail.

First, Baran correctly notes that the "release means for retaining the guide in the charged position" limitation, as construed by the Court, does not require a release that is suitable for performing a biopsy. Adding this requirement would impermissibly add an unclaimed limitation. *Applied Medical*, 448 F.3d at 1339 (Dyk, J., dissenting) ("a court may not import unclaimed functions into a means-plus-function limitation"). Therefore, although it is undisputed that Baran's crank arm structure for releasing and retaining the guide cannot perform the release function in a manner suitable for a biopsy, this is irrelevant. *Id.* Second, pulling up on the

crank arm does release the guide from the charged position, as was clear from the experts' demonstrations depicted in their video depositions. (MSJ, Exs. E, F.) It does *not* release the guide from the slider-crank mechanism, but, again, that is not required by the Court's construction of this limitation. Further, the slot in the crank arm does retain the guide in the charged position, at least to the extent that the guide cannot remain in the charged position unless the latching projection is engaged in the slot. (*Id.*)

Accordingly, the Court finds that the structure identified by Baran performs the identical functions disclosed in the '797 Patent for the releasing and retaining limitation. That is, "*retaining* the guide in the charged position and *releasing*, or setting free, the guide from the charged position." (*Markman* Opinion at 30-31.)

d. Structural Equivalence: the "way" and the"result"

Having found that the structure identified by Baran in the BioPince performs the retaining and releasing functions disclosed in the '797 Patent, the final step of the analysis is to determine whether that structure performs the "function in substantially the same way to achieve substantially the same result as the corresponding structure described in the specification." *Odetics*, 185 F.3d at 1267 (citing 35 U.S.C. § 112 ¶ 6). It is on this stage that Baran falls off the tight-rope.

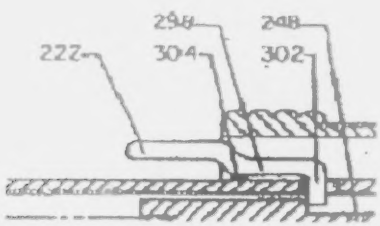
Appendix E

The structures Baran identifies as performing the releasing and retaining functions consists of (referring to Figures 12 and 13, reproduced below) the crank arm 55, with the opening in the crank arm 85, and the shoulder within the opening 80; as well as the release "lever" 65 , with the latching projection 70 and the mounting section 75.

(Figure 12)

(Figure 13)

In the *Markman* Opinion, the Court identified the corresponding structures in the '797 Patent as "the release lever 222, including latching projection 302, the finger rest (not marked by a reference numeral), and the mounting section 298, as well as the equivalents thereof." (*Markman* Opinion at 33 (depicting Figure 5-8A of the '797 Patent, which is reproduced at right).)



Appendix E

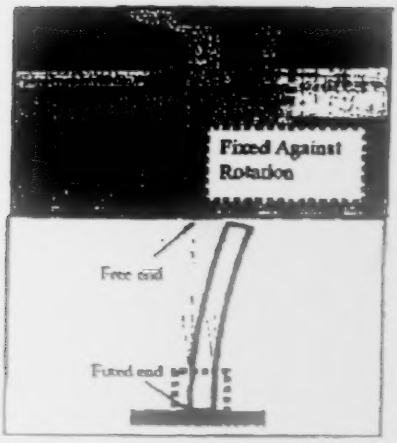
In order to prove infringement, Baran must show that the structures he identifies in the BioPince, "perform[s] [the releasing and retaining] function[s] in substantially the same way with substantially the same result" as the corresponding structures in the '797 Patent (keeping in mind the rule against a component-by-component analysis). *See Odetics*, 185 F.3d at 1267 (emphasis added).

The Corresponding Structures Do Not Perform the Function in Substantially the Same Way

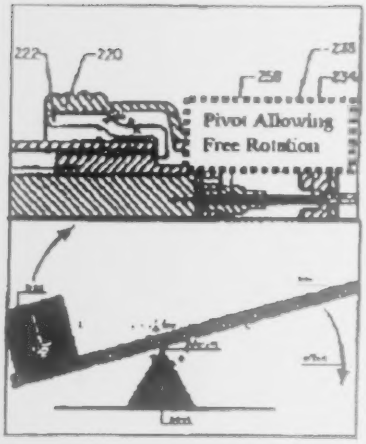
MDTech argues that the overall structures disclosed in the '797 Patent and identified by Baran in the BioPince for the releasing and retaining functions perform those functions in substantially different ways. First, MDTech contends that the structure at the heart of Baran's crank arm method for releasing the BioPince is a cantilever, while the corresponding structure central to the releasing function disclosed in the '797 Patent is the release lever 222. MDTech argues that the physical and scientific characteristics of a cantilever and a lever are definitively established and scientifically distinct. As explained by Dr. Rashidi, levers pivot around a fulcrum; cantilevers flex when force is applied to their free end. (Reply at 12.) MDTech further notes that this distinction is quantifiable in terms of the force necessary to move the latching projection of the BioPince and the release lever element of the '797 Patent. MDTech illustrates its comparison of a cantilever and a lever as follows:

Appendix E

The BioPince Cantilever



The '797 Patent's Lever



(Reply at 13.) MDTech argues, moreover, that the way in which the releasing is performed magnifies the physical distinctions between the structures in the BioPince and the corresponding structures disclosed in the '797 Patent. Whereas the user must pry up on the crank arm of the BioPince to release it from the cantilever latching projection, the '797 Patent teaches releasing the guide by pressing down on the finger rest of the release lever 222 to raise the latching projection 302 on the other end of the release lever.

Baran argues that MDTech's analysis is an improper component-by-component approach focused on just one component of the relevant structure — the release lever. In addition, Baran argues that the flexing of the cantilever in the BioPince is substantially equivalent to the flexing of the release lever in the claimed invention. Baran contends that the way in which the corresponding

structures in the BioPince and the claimed invention perform the releasing function is substantially the same because both the crank arm and the release lever "move upwards" to free the guide. (Opp'n Br. at 25.)

While the Court is cognizant of the need to avoid a component-by-component analysis, MDTech correctly notes that it is not improper to give special attention to a particularly important component of the relevant corresponding structures. *See Solomon Techs., Inc. v. Int'l Trade Comm'n*, 524 F.3d 1310, 1317 (Fed. Cir. 2008) (allowing "for greater weight to be given to individual components that play a central role in the identified structure"). The Court finds that the cantilever/latching protrusion in the BioPince and release lever in the claimed invention are such structures with respect to the releasing function. These structures play an essential role in releasing the charge in the BioPince and the claimed invention.

The Court is also persuaded by MDTech's argument that no reasonable juror could find that the corresponding structures — one of which is primarily characterized by a cantilever and the other a lever — perform the function in substantially the same manner. First, the differences between a cantilever and a lever are elementary scientific principles beyond legitimate dispute. (*See* Rashidi Dep. at 248-49.) As Rashidi explained in some detail at his deposition, a lever employs a fulcrum and multiplies effort, while a cantilever is a beam that is anchored at one end and flexes at the other. (*Id.*) Just as a see-saw and a diving

board do not function in substantially the same ways in lifting a child to exciting heights, a lever and a cantilever do not release the guide in substantially the same way. Among other things, a lever pivots on a fulcrum while a cantilever flexes. Therefore, Baran's argument that the "flexing" of the release lever and the cantilever/latching protrusion is substantially equivalent is nonsensical. Although Baran attempts to minimize this distinction by referring to a cantilever as a "flexible lever," the Court is persuaded by comparisons of the scientific principles at work, not semantics. Baran' s expert, Haaga, moreover, completely failed to articulate a plausible explanation at his deposition of how the structures associated with the crank arm release method and corresponding structures in the claimed invention perform the releasing function in substantially the same way. (Haaga Dep. at 194-198, 217-218.)

Baran attempts to overcome the clear and manifest difference between a lever and a cantilever by defining the "way" in which the structure performs the function very generally — *i.e.*, as "upward motion" to release the guide. This is clever (especially within the context of a relatively complex multi-step analysis); however, it improperly conflates two parts of the § 112 ¶ 6 analysis. Namely, Baran's articulation of the "way" of performing the releasing function adds virtually nothing to the function itself. The way in which the releasing function is performed by the corresponding structures involves far more than an "upward motion." Although the Court has found (above) that the "identical function" requirement is satisfied here, it will not permit Baran

to bootstrap the remaining requirements to that finding. Accordingly, Baran cannot satisfy the test for statutory equivalents because the way in which the BioPince and the claimed invention perform the releasing function are not substantially equivalent.

The Actions of the Corresponding Structures Do Not Lead to Substantially the Same Result

Baran uses the same over-generalization tactic to argue that the result of the release of the BioPince and the claimed invention is substantially the same. In fact, Baran expressly states that "the result is simply the release of the guide." (Opp'n Br. at 26.) In support of this broad characterization of the result, Baran contends that whether the release is one which could actually be used to perform a biopsy is irrelevant because "[t]he claim is directed to a biopsy instrument, not a method for performing a biopsy." (*Id.*) Consequently, Baran argues that it is irrelevant that, compared to the release method taught by the claimed invention, the crank arm method for releasing the BioPince produces a release that (1) is not suitable for taking a biopsy; (2) is clearly more violent and erratic; and (3) leaves the device in a half-cocked position.

It is true that claim 7 of the '797 Patent does not claim a method for performing a biopsy. This statement properly focuses the analysis on the claims of the patent at issue. That same focus reveals the flaw in Baran's argument, however. The claims of the '797 Patent do not teach a slow-release, erratic means of dry-firing the

claimed invention. The means-plus-function limitation, as construed by the Court, recites the following function: "retaining the guide in the charged position and releasing, or setting free, the guide from the charged position." To say that, for purposes of the statutory equivalents analysis, the result is that the guide is retained and then released deprives the result prong of any meaningful role in the analysis. Therefore, the purpose of the invention and its specifications must inform the analysis of whether the result is substantially the same. The '797 Patent claims an automated biopsy instrument. Whether the structures for performing the releasing function are capable of a release appropriate for taking a biopsy must be relevant to the analysis of whether the result is substantially the same. Applying this principle here, because it is undisputed that the crank arm release method is not appropriate for taking a biopsy, the result is not substantially the same unless the purpose of the claimed invention is irrelevant. Accordingly, the last requirement of statutory equivalence is not satisfied as a matter of law and MDTech is entitled to summary judgment of noninfringement.

III. CONCLUSION

In summary, MDTech is entitled to summary judgment of noninfringement because there is no genuine issue of fact sufficient permit a reasonable jury to conclude that either of the following limitations of claim 7 of the '797 Patent is infringed:

(1) "a manually operable charging member for moving the guide to the charged position against the urging of the coil spring" and,

(2) "a release means for retaining the guide in the charged position."

For the foregoing reasons, Baran's *Motion for Leave to File Sur-Reply* (Doc. 181) is **DENIED**, MDTech's *Motion for Summary Judgment of Noninfringement* (Doc. 164) is **GRANTED** and this case is **DISMISSED**.

IT IS SO ORDERED.

/s/
KATHLEEN McDONALD O'MALLEY
UNITED STATES DISTRICT JUDGE

Dated: September 30, 2009

APPENDIX F — OPINION AND ORDER OF THE UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF OHIO EASTERN DIVISION DATED SEPTEMBER 25, 2007

UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF OHIO EASTERN DIVISION

Case No. 1:04cv1251

GREGORY W. BARAN, M.D.,

Plaintiff,

v.

MEDICAL DEVICE TECHNOLOGIES, INC., et al.,

Defendants.

JUDGE KATHLEEN O'MALLEY

OPINION AND ORDER

Plaintiff Gregory W. Baran, M.D. ("Baran" or "Plaintiff") brings this patent infringement suit against Defendants Medical Device Technologies, Inc. ("MDTech"), Gedon AB ("Gedon"), Ascendia AB ("Ascendia"), and Anders H. Weilandt ("Weilandt") (Gedon, Ascendia, and Weilandt are hereinafter collectively referred to as "the Swedish defendants"), alleging infringement of two patents directed at an automated biopsy instrument that, according to the Complaint,[1] are issued to and owned by Baran. Specifically, Baran alleges in his Complaint that (1) the

1. "Complaint" refers to Dr. Baran's *Second Amended Complaint for Willful Patent Infringement* (Doc. 60).

Appendix F

Swedish defendants have infringed rights that Baran holds in U.S. Patent Nos. 5,025,797 ("the '797 patent") and 5,400,798 ("the '798 patent") by offering for sale, selling and/or distributing the BioPince and Express biopsy instruments in the United States, and (2) MDTech has infringed Baran's rights in the '797 and '798 patents by importing, offering for sale, and/or selling the BioPince biopsy instrument in the United States. Baran alleges that all defendants have directly and/or indirectly infringed one or more claims of the '797 and '798 patents and that such infringement was willful and deliberate. Pursuant to *Markman v. Westview Instruments*, 517 U.S. 370 (1996), this Opinion and Order construes, as a matter of law, the disputed claim terms of the patents at issue in this case.

I. BACKGROUND

Baran is an individual residing in Ohio who is the inventor of the claimed subject matter of the '797 and '798 patents. MDTech is a Delaware corporation with its principal place of business in Gainesville, Florida. Among others, MDTech imports and sells the BioPince biopsy instrument, one of the alleged infringing devices in this case. In response to Plaintiff's Complaint, MDTech has answered and asserted counterclaims for declaratory judgment of non-infringement as to both patents.

The status of the Swedish defendants in this matter is more complicated for a variety of reasons, and the Court is unaware of their status and participation in this

case at this time.[2] Indeed, as of the date of this opinion, none of the Swedish defendants have participated in any substantive aspect of this case, including claim construction, either by way of written submissions or oral argument. Based on the way this case has proceeded, it appears that there is not likely to be any active participation by the Swedish defendants as it relates to the substantive question of infringement. As such, although the Court postponed the originally scheduled claim construction hearing in this matter while the questions of service and personal jurisdiction as to one Swedish entity were being investigated and briefed, and while Plaintiff was determining the proper entities to be named as defendants in this case, it ultimately proceeded with a claim construction hearing without the Swedish defendants so as not to further delay the case. In any event, Plaintiff alleges that MDTech imports and sells the same accused device - the BioPince - that the Swedish defendants are alleged

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2. As the docket of this case reflects, there have been a number of issues involving the Swedish defendants relating to the proper entities or persons to be named as defendants, the adequacy of service of those defendants, and the Court's personal jurisdiction over them. The Court does not now detail those issues, other than to note that efforts at resolving those issues were stonewalled by the conduct of counsel for AMT Sverige AB (a defendant named in the First Amended Complaint that, according to Plaintiff, entered into voluntary dissolution in part to avoid this litigation), a tactic that this Court ultimately found to be in violation of the Federal Rules of Civil Procedure and this Court's inherent powers. That strategy resulted in sanctions. It also delayed the efficient progression of this case and, ultimately, left the status of the Swedish defendants in this matter uncertain.

to have distributed. In addition, the other allegedly infringing biopsy instrument the Swedish defendants distribute - the Express - apparently is identical to the BioPince except for the color of its handle. All claim construction issues are, accordingly, sufficiently ripe for this Court's consideration.

Prior to the *Markman* hearing, according to the initial Case Management Plan in this matter, Plaintiff and MDTech first submitted a joint claims construction chart, identifying areas of agreement and areas of dispute; later, they submitted separate briefs urging a certain construction for each disputed claim term. The initial claims construction chart indicated that the parties[3] were in dispute over the construction of ten terms contained in claim 7 the '797 patent and ten terms contained in claim 2 of the '798 patent. As often happens, however, the parties' subsequent briefing narrowed the issues substantially, and the parties' briefs focused only on those terms that the parties agreed may be outcome determinative, a number totaling seven terms between the two patents.

Having considered the parties' briefing and oral arguments, the Court sets out its analysis and construction of the disputed claim language below, after first outlining the applicable legal standards.

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3. The "parties" hereinafter refers to Baran and MDTech, as those were the only two parties participating in the claim construction process in this matter.

Appendix F

II. LEGAL STANDARDS

The construction of a patent and the terms contained therein is an issue to be determined by the Court, as a matter of law. *Markman*, 52 F.3d at 976, *aff'd*, 517 U.S. 370, 372 (1996). In construing a claim, the Court determines "the meaning and scope of the patent claims asserted to be infringed." *Id.* Construction of the claims is the first step in a "two-step analysis" of infringement. *Elekta Instrument S.A. v. O.U.R. Scientific Int'l., Inc.*, 214 F.3d 1302, 1306 (Fed. Cir. 2000).

"In construing claims, the analytical focus must begin and remain centered on the language of the claims themselves, for it is that language that the patentee chose to use to 'particularly point [ ] out and distinctly claim[ ] the subject matter which the patentee regards as his invention.'" *Interactive Gift Express, Inc. v. Compuserve, Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001) (quoting 35 U.S.C. § 112, ¶ 2); *see also Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) ("the claims themselves provide substantial guidance as to the meaning of particular claim terms"). To ascertain the meaning of the claims, a court primarily should consider three things: the language of the patent claims, the patent specification, and the prosecution history. *Insituform Techs., Inc. v. Cat Contracting, Inc.*, 99 F.3d 1098, 1105 (Fed. Cir. 1996); *Markman*, 52 F.3d at 979. The claim language itself defines the scope of the claim, and "a construing court does not accord the specification, prosecution history, and other relevant evidence the same weight as the claims themselves, but consults these

sources to give the necessary context to the claim language." *Eastman Kodak Co. v. Goodyear Tire & Rubber Co.*, 114 F.3d 1547, 1552 (Fed. Cir. 1997) (overruled on other grounds by *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448 (Fed. Cir. 1998)). Thus, a court should construe claim terms as having the meaning ascribed to them by one of ordinary skill in the art unless the patent specification or prosecution history indicates a contrary meaning. *Phillips*, 415 F.3d at 1313 ("the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification."); *see also Northern Telecom Ltd. v. Samsung Electronics*, 215 F.3d. 1281, 1287 (Fed. Cir. 2000) ("Claim language is given its ordinary and accustomed meaning except where a different meaning is clearly set forth in the specification or where the accustomed meaning would deprive the claim of clarity.")

In determining the meaning to be given claim terms, those terms must be read in the context of the specification because it is the patent specification which, by statute, must contain a "full, clear, concise, and exact" description of the invention. 35 U.S.C. § 112, ¶ 1; *Phillips*, 415 F.3d at 1311. Thus, claim terms must be construed so as to be consistent with the specification. *Id.* at 1315. But that does not change the fact that it is the language of the claim that is being construed, and not the specification. *See id.* at 1312-13, 1316 ("The construction that stays true to the claim language and most naturally aligns with the patent's description of

the invention will be, in the end, the correct construction." (quoting *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998))).

In some circumstances, the specification may teach that a claim term is to be given a meaning which differs from the ordinary meaning of such term. For example, the patentee may use the specification as a sort of dictionary, by defining expressly the terms used in the claims. *Markman*, 52 F.3d at 979. In such instances, the patentee is deemed to have acted as his own lexicographer, and it is those definitions, even if they dictate unusual meanings for the language employed, which must control. *Texas Digital*, 308 F.3d at 1204.

Care must be used in reading the specification, however, because while a patentee can "act as his own lexicographer to specifically define terms of a claim contrary to their ordinary meaning, the written description in such a case must clearly redefine a claim term so as to put a reasonable competitor or one reasonably skilled in the art on notice that the patentee intended to so redefine that claim term." *Elekta*, 214 F.3d at 1307 (quoting *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357 (Fed. Cir. 1999)) (internal quotation marks omitted).

Although claims must be read in view of their specification, the Federal Circuit repeatedly has cautioned against limiting the scope of a claim to the preferred embodiment or specific examples disclosed in

the specification. *See Ekchian v. Home Depot, Inc.*, 104 F.3d 1299, 1303 (Fed. Cir. 1997) ("While examples disclosed in the preferred embodiment may aid in the proper interpretation of a claim term, the scope of a claim is not necessarily limited by such examples"); *Intervet America, Inc. v. Kee-Vet Labs., Inc.*, 887 F.2d 1050, 1053 (Fed. Cir. 1989) ("limitations appearing in the specification will not be read into claims, and . . . interpreting what is meant by a word in a claim 'is not to be confused with adding an extraneous limitation appearing in the specification, which is improper'") (emphasis in original) (citation omitted). Similarly, both the Federal Circuit and the Supreme Court have cautioned against using the specification to expand the scope of the claims. *Johnson & Johnston Assocs. Inc. v. R.E. Service Co., Inc.*, 285 F.3d 1046, 1052 (Fed. Cir. 2002) (citing *McClain v. Ortmayer*, 141 U.S. 419, 424 (1891) ("The claim is the measure of [that patentee's] right to relief, and while the specification may be referred to to limit the claim, it can never be made available to expand it.")).

Beyond the specification, the Court may also look to the patent's prosecution history if it is a part of the record in the case. *Markman*, 52 F.3d at 980. "This 'undisputed public record' of proceedings in the Patent and Trademark Office ["PTO"] is of primary significance in understanding the claims." *Id.*; *Phillips*, 415 F.3d at 1317 ("Like the specification, the prosecution history provides evidence of how the PTO and inventor understood the patent.") Again, however, although the prosecution history "can and should be used" when

construing the claims, it "cannot 'enlarge, diminish, or vary' the limitations in the claims." *Markman*, 52 F.3d at 980 (citation omitted).

In addition to the intrinsic record, the Court may also consider extrinsic evidence such as dictionaries, encyclopedias, treatises and inventor and expert testimony to assist it in understanding the technology at issue or in determining the meaning or scope of terms in a claim. *Phillips*, 415 F.3d at 1317-18; *see also Aqua-Aerobic Sys., Inc. v. Aerators, Inc.*, 211 F.3d 1241, 1244-45 (Fed. Cir. 2000); *Hoechst Celanese Corp. v. BP Chemicals Ltd.*, 78 F.3d 1575, 1579 (Fed. Cir. 1996), *cert. denied*, 117 S.Ct. 275 (1996). While such evidence is generally considered less reliable than the intrinsic record (for a variety of reasons), the Court is free to consider it, and may do so at any stage of its inquiry. *Phillips*, 415 F.3d at 1318-19; *see also Free Motion Fitness, Inc., v. Cybex Int'l, Inc.*, 423 F.3d 1343, 1348-49 (Fed. Cir. 2005).

A final claim construction principle must also be mentioned in the context of this case: socalled means-plus-function claiming pursuant to 35 U.S.C. § 112, ¶ 6. Section 112, ¶ 6 provides that:

> An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification or equivalents thereof.

This paragraph "allows a patentee to recite a function to be performed as a claim limitation rather than reciting structure or materials for performing that function." *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1321 (Fed. Cir. 2003). In determining whether Section 112, ¶ 6 applies, the Federal Circuit has explained that "the use of the word 'means' triggers a presumption that the inventor used this term advisedly to invoke the statutory mandates for means-plus-function clauses." *York Products, Inc. v. Central Tractor Farm & Family Center*, 99 F.3d 1568, 1574 (Fed. Cir. 1996). Two rules, however, may overcome that presumption. First, "a claim element that uses the word 'means' but recites no function corresponding to the means does not invoke § 112, ¶ 6." *Rodime PLC v. Seagate Tech., Inc.*, 174 F.3d 1294, 1302 (Fed. Cir. 1999). Second, "even if the claim element specifies a function, if it also recites sufficient structure or material for performing that function, § 112, ¶ 6 does not apply." *Id.*

Once a court determines that § 112, ¶ 6 applies, construction of a means-plus-function term involves two steps. First, the court must identify the claimed function, "staying true to the claim language and the limitations expressly recited by the claims." *Omega Eng'g, Inc.*, 334 F.3d at 1321. Next, a court must "ascertain the corresponding structures in the written description that perform those functions." *Id.* A structure is corresponding "only if the specification or the prosecution history clearly links or associates that structure to the function recited in the claim." *Id.* (*quoting B. Braun Med., Inc. v. Abbott Labs.*, 124 F.3d 1419, 1424 (Fed. Cir. 1997)).

With all of these principles in mind, the Court turns to the parties' dispute over the claim language employed in the patents at issue in this case.

III. CONSTRUCTION ANALYSIS

A. Overview of the Invention[4]

As mentioned at the outset, Baran's patents are directed at an automated biopsy instrument. To give context to Baran's invention and the problems it was intended to remedy, the Court first reviews biopsy instruments in general before addressing Baran's specific invention.[5]

A biopsy instrument, generally, is a device for removing a sample of tissue from a human being or animal for diagnosis. Prior to the advent of biopsy instruments, tissue specimens primarily were obtained through invasive exploratory surgery. Biopsy instruments enabled medical professionals to obtain

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4. The claims at issue in this case, although from two different patents, refer to the same invention. The '798 patent is a later filed Continuation-in-Part of the '797 patent, but the new matter introduced in the '798 patent is not at issue here. The portions of the '797 specification and '798 specification relevant to the Court's analysis, therefore, are nearly identical. To avoid redundancy, the Court cites only to the '797 specification in providing a general overview of the invention.

5. The following information was gleaned by the Court from the parties' briefs, the parties' oral arguments, the prior art disclosed in the patents at issue, and the patents themselves.

tissue samples with less risk of trauma and damage to a patient. Most contemporary biopsy instruments remove the tissue sample through the use of a two part needle set comprised of a stylet, which is a slender probe or wire, and a cannula, which is a hollow tube that surrounds the stylet and can be inserted into the body. The cannula, and sometimes the stylet, are sharp or pointed so that they are capable of cutting through or piercing tissue.

There are two primary methods of obtaining a tissue specimen that the parties described in their briefs and at the *Markman* hearing. Each method involves the use of a different type of needle. The first method employs a slotted needle, which includes a sharpened stylet containing a gap near its distal end (the end farthest from the point of attachment) that acts as a tissue pocket. An illustration of a slotted needle, taken from Figure 9 of the '797 patent, is shown to the right. As described in the specification as one type of needle the invention can utilize, the stylet **60*a*** contains a gap **60*b*** near its sharpened distal end **78*a*.** ('797 patent, col. 8, l. 26-32.) The tube not identified in Figure 9 surrounding the left portion of the stylet is the cannula. When using a slotted needle, the user first inserts the stylet into the desired tissue area with the cannula retracted, or not covering the stylet. The user then advances the cannula over the stylet, capturing the tissue in the slot or gap in the stylet. The entire needle is then withdrawn from the patient, with the sample still captured in the slot.

Appendix F

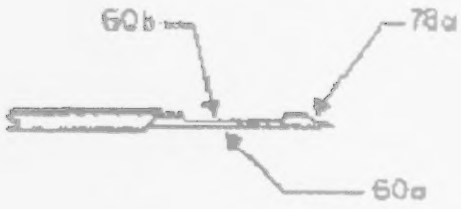

FIG. 9

The other method involves a full-core needle, which, as the name implies, employs a stylet that does not contain a slot or gap. With this method, the cannula extends beyond the stylet and is inserted into the tissue. The tissue sample fills the hollow portion of the cannula. Once the needle is withdrawn from the patient, the stylet can then be advanced into the cannula to eject the sample from the cannula. Typically, this method requires some sort of negative pressure or suction to ensure that the specimen actually stays inside the cannula when it is withdrawn. Counsel for MDTech analogized this method to putting a straw in a cola bottle - a user needs to put his finger over the straw when it is removed in order to capture some cola in the straw. (Transcript from *Markman* Hearing (hereinafter, "Tr."), at 76.)

Each method has advantages and disadvantages. The slotted needle method has the advantage of being more likely to obtain the specimen when the needle is withdrawn because it literally traps the specimen in the needle. Because the full-core needle does not trap the specimen and typically requires negative pressure or

suction, it is less likely that it will be successful in removing the specimen. The disadvantages of the slotted needle, however, are that the size and weight of the specimens that this needle obtains are smaller because the entire cannula tube is not filled with the tissue specimen, as with the full-core needle. In addition, the slotted needle is limited in that smaller sized needles cannot be used. This is because the stylet of the slotted needle is thinner than the full core needle and, therefore, becomes more flexible and less stable at smaller sizes. This becomes an issue because certain tissue masses apparently require the use of smaller needles. Conversely, while the full-core needle is advantageous because it provides a larger (and, therefore, potentially better) sample size and can accommodate smaller needle sizes, it is not as consistent in actually obtaining the desired specimen. As it relates to the issues before the Court, it is important to note that each needle is desirable in different situations.

In different biopsy instruments, movement of the stylet and cannula can be manual, semiautomated, or automated. A manually operated biopsy device, of course, requires the user to move the cannula and the stylet by hand. The semi-automated and automated biopsy instruments, however, contain some sort of part or mechanism to move either the cannula, the stylet, or both. For example, the patents at issue in this case describe prior art that discloses an instrument in which an electrical motor powers a pair of serrated scalpel blades (U.S. Patent No. 3,452,741 (1969)), in which a stylet is manually advanced and the cannula is released

by depressing a trigger (U.S. Patent No. 4,667,684 (1987)), in which a spring-loaded stylet advances into the tissue followed by a delayed release of a spring-loaded cannula (U.S. Patent No. 4,699,154 (1987)), and in which a slidable stylet is manually advanced into the tissue mass and a spring-loaded cannula is released and driven over the stylet (U.S. Patent No. 4,600,014 (1986)). The benefits of the semi-automated and automated devices over the manual devices are that the cutting motion is swifter, which causes a cleaner cut, does less damage to the surrounding tissue, and shortens the length of the procedure; the automated devices are more accurate; and there is less risk of inherent human error in operating the cannula and stylet.

With that background, the Court now turns to the patents at issue in this case. The '797 patent was filed on March 29, 1989 and issued on June 25, 1991, and the '798 patent was filed as a Continuation-in-Part of the '797 patent on April 23, 1993 and issued on March 28, 1995. As the prior art above shows, the invention disclosed in these patents was not the first for an automated biopsy instrument; it was an improvement on existing automated instruments. In the Background of the Invention, the patent identifies certain problems with instruments known at the time, primarily related to the ease of use and risk of accident. Specifically, the patent explains that "the various automated biopsy instruments presently known tend to be heavy, difficult to manipulate, and incorporate biasing mechanisms[6] which are either complicated in construction or require

undue force to operate." ('797 patent, col. 3, l. 8-12.) In addition, the Background of the Invention identifies the possibility of "inadvertent movement or torque," especially in the case of instruments that permit or require elements to be manually adjusted prior to advancement of the cannula. (*Id.*, col. 3, l. 14- 20). Likewise, some instruments contain a moveable stylet that extends beyond the rear of the instrument, leaving it vulnerable to accidental impact and inadvertent advancement into the body. (*Id.*, col. 2, l. 37-47.) Finally, the Background of the Invention notes that the known instruments have exposed triggers or releases that actuate the movement of the cannula or stylet, thus further creating the risk of accidental advancement of the cannula. (*Id.*)

To address those perceived problems, the '797 patent provides an instrument with a stationary stylet that, once mounted to the instrument, cannot be moved inadvertently or otherwise. (*Id.*, col. 3, l. 30-35.) It also describes a guide on which a cannula can be mounted that can be manually moved to the charged position against the urging of a biasing mechanism such as a coil spring, and can be released to the discharged position, advancing in the direction of the stylet by a manually actuable release means. (*Id.*, col. 2, l. 35-44.) To address the problem of an exposed trigger or release, the patent describes that, "[i]n the preferred embodiments of the invention, a shield means is provided which is disposed

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6. Biasing mechanisms are the mechanisms that charge and discharge the cannula and the stylet for advancement into the tissue. The parties agree on the meaning of this phrase.

to block or prevent inadvertent actuation of the release means." (*Id.*, col. 2, 1. 58-60.) In addition, the patents contain preferred embodiments that can employ both the slotted needle and the full-core needle interchangeably.

There are two basic embodiments in the '797 and '798 patents. One embodiment, depicted in Fig. 1 of both patents, relates to a reusable configuration that permits needle sets to be used and replaced, so that the instrument can be used multiple times for multiple patients. The second embodiment, depicted in Fig. 5 of both patents, relates to a single use configuration that can be used on only one patient. An exploded view of the first embodiment, taken from Fig. 1, is shown on the next page:

Appendix F

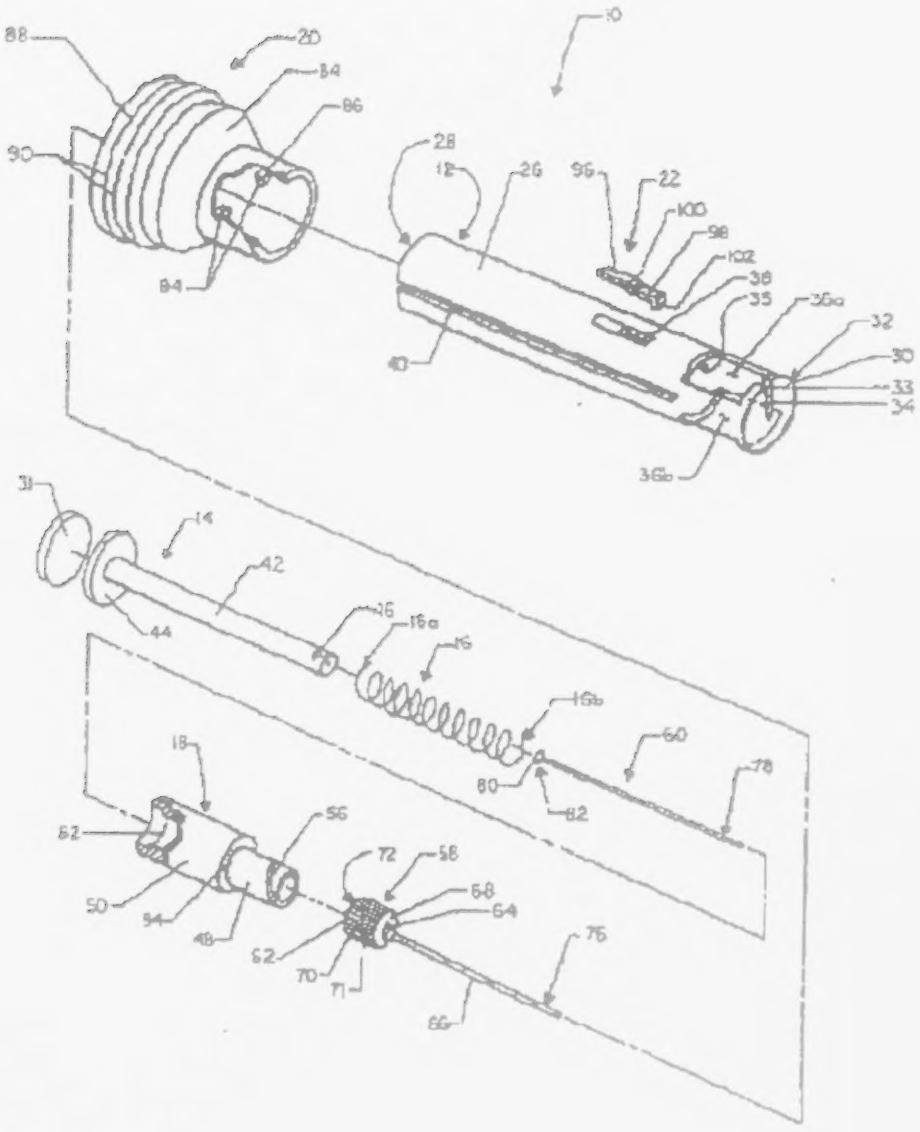

FIG. 1

Appendix F

The automated instrument 10 as shown in Fig. 1 includes the following primary components: an outer casing 12; a support rod 14; a coil spring 16; a biopsy spring guide 18; a safety cap 20; a release lever 22; and a needle 24. ('797 patent, col. 4, l. 47-51.) A needle 24 is not shown in this illustration (it is shown in Figure 1A), but it comprises a stylet 60 and a cannula mount 58, which, in turn, comprises a cylindrical collar 62, a conical head 64, and a cutting cannula 66. (*Id.*, col. 4, l. 37-40.) Although the operation of the device depicted in Fig. 1 will be discussed in greater detail below in the context of the disputed claim language, some points are worth noting here.

According to the Detailed Description of the Invention, the instrument is converted from the discharged mode to the charged-safety-on mode (meaning it is ready to fire, but there is a shield over the release) by retracting the safety cap 20 toward the rear end 28 of the tube 26. (*Id.*, col. 7, l. 4-7.) This action causes the guide pins 94 to engage the annular external shoulder 54 of the spring guide 18 to retract the spring guide toward the base 44 of the support rod 14 and compress the coil spring 16. (*Id.*, col. 7, l. 12-16.) In other words, according to that description, the charge is created when the safety cap is pulled backward and the guide pins on the inside of the safety cap structure catch the shoulder of the spring guide, which compresses the spring back toward the base. This action creates the charge that, once the release is pressed, causes the cannula to advance forward over the stylet.

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As between Fig. 1 (the reusable embodiment) and Fig. 5 (the single use embodiment), the most significant difference for purposes of the Court's present analysis is the cannula mount, specifically the cannula mount's interaction with the spring guide. The relevant portion of Fig. 5 is shown to the right. As depicted, rather than have a screw-on feature like the cannula mount in Fig. 1, this embodiment has a plug-in type feature, where the cannula mount **258** receives the cannula **266** on one end and plugs into the guide **218** by inserting the base **262** into a bore **255*a*** in the guide.

These descriptions of the invention are meant to provide some background to the claims at issue in this case. The remaining elements of the invention will be discussed below, where applicable, in the context of the disputed claim language.

B. Disputed Claim Terms

Plaintiff alleges that the accused devices infringe claim 7 of the '797 patent and claim 2 of the '798 patent. Below are the claims in full, with the disputed terms in bold:

> 7. A biopsy instrument comprising an elongate hollow casing, a needle extending outwardly from the casing and having a cannula and a stylet received within the cannula, a stationary support mounted within the casing in fixed relation thereto and having means affixing the stylet thereto, a cannula guide, **a cannula mount affixing the**

cannula to the guide, the guide being completely enclosed by the casing for reciprocating movement therewithin relative to the stationary support between a charged position, wherein the cannula is retracted in a direction away from the distal end of the stylet, and a discharged position, wherein the cannula is displaced from the charged position in the direction of the distal end of the stylet, a coil spring engaged between the stationary support and the guide for urging the guide toward the discharged position, **a manually operable charging member for moving the guide to the charged position against the urging of the coil spring**, and **a release means for retaining the guide in the charged position.**

('797 patent, col. 12, l. 54 - col. 13, l.5.)

2. An apparatus for acquiring biopsy specimens, the apparatus comprising in combination:

a) **a biopsy actuator**;

b) a cannula having a predetermined inner diameter and having a distal end for insertion into a patient and having an opposing proximal end, **said proximal end having a first connector means secured thereto**;

c) a stylet means attached to the biopsy actuator, the stylet means having a predetermined outer diameter commensurate with the predetermined inner diameter of said cannula and adapted to slide into said cannula through the proximal end of said cannula, said stylet means having a distal end for closing the distal end of said cannula during insertion of said cannula into a patient, **said stylet means being detachable from said cannula**;

d) **said biopsy actuator comprising a second connector means for releasably and fixedly engaging the first connector means**, wherein the first connector means and the second connector means are movable as a unit during acquisition of the biopsy specimen,

e) said biopsy actuator comprising means for rapidly advancing the distal end of said cannula beyond the distal end of the stylet means to acquire a core biopsy specimen.

('798 patent, col. 14, l. 50 - col. 15, l. 8.)

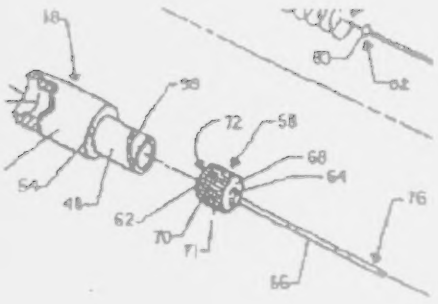
Appendix F

1. "a cannula mount affixing the cannula to the guide"

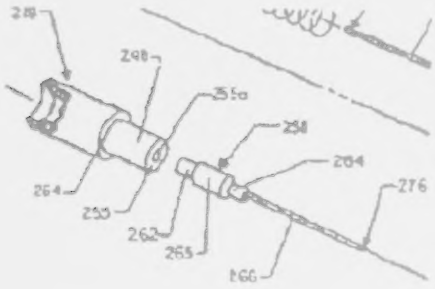
Plaintiff proposes that this term should be construed to mean "anything that affixes or connects the cannula to the guide." MDTech's proposed construction is "a support which attaches the cutting cannula to the guide in a secured manner." At oral argument, counsel for MDTech agreed that the word "cutting," which Plaintiff found objectionable, could be removed from MDTech's proposed definition, and further agreed that "structure" could be substituted for "support" in the proposed definition. (Trans. at 92 - 93.) The only real dispute between the two proposed constructions, therefore, is whether the "cannula mount" can be "anything," as Plaintiff proposes, or whether it must be a "support" or "structure," as MDTech argues it should.

A cannula mount, depicted as item 58 in the Fig. 1 embodiment, is shown to the right. The Fig. 1 embodiment depicts the cannula mount 58 configured to receive the cannula 66 at one end near its conical head 64 and to attach to the guide 18 at the other end by engaging the cannula mount's internal threaded portion 72 (the female thread) with the external threaded portion 56 (the male thread) of the guide 18. In other words, the cannula mount in this illustration joins the cannula to the guide by securing the cannula on one end and having a screw-like connection with the guide on the other.

Appendix F



In the Fig. 5 embodiment shown to the right, the cannula mount **258** receives the cannula **266** on one end and plugs into the guide **218** by inserting the base **262** into a bore **255*a*** in the guide. The specification explains that the cannula mount **258** is adhesively bonded within the bore **255*a***. ('797 patent, col. 9, 38 - 43.)



Plaintiff argues that both embodiments show the cannula mount joining the cannula and the guide and, therefore, that the mount can be "anything" that affixes

these two components together. In addition, Plaintiff argues that defining this term as requiring a support or structure is impermissibly interpreting it as means plus function claim.

MDTech, on the other hand, argues that the word "anything" gives too broad of a construction to this term, and that "anything" could include glue, velcro or other materials that can attach or affix components and that are not themselves structures. MDTech argues that such a construction is in conflict with both the intrinsic and extrinsic sources to which the Court may refer. First, MDTech points to language in the detailed description of the invention, explaining that "the proximal end 282 of the stylet 262 [sic] is adhesively bonded within the recess, and the base 262 of the cannula mount 258 is similarly secured within the bore 255*a*." ('797 patent, col. 9, l. 40-43). MDTech argues that, if the cannula mount can be secured with adhesive, the cannula mount itself cannot be adhesive and, therefore, it cannot be just "anything."

In addition, MDTech argues that the prosecution history reveals that this claim was amended to add the phrase "cannula mount" in order to obtain allowance of the claim. Prior to the examiner's amendment, the claim read, "a guide having means affixing the cannula thereto." (MDTech Claim Construction Brief, Doc. 54, Ex. 4, at GWB 00086.) The examiner's amendment changed that language to its current form. (*Id.*, at GWB

00068.) MDTech argues that the reason for the change was the submission of additional prior art references, one of which (the Portner patent) showed a guide directly gripping the cannula, as opposed to having a structure joining the two components. The change, MDTech argues, was meant to incorporate some structure that attached the guide to the cannula rather than having them directly attached or bonded together. Plaintiff offers no alternative explanation for this amendment.

Finally, MDTech argues that a common dictionary definition of the noun "mount" is "FRAME, SUPPORT: as a material (cardboard) on which a picture is mounted." (MDTech Br., Ex. 6.); *see also* Merriam-Webster Online Dictionary, *www.m-w.com* (same). MDTech points out that this definition is consistent with the Fig. 1 and Fig. 5 embodiments, both of which refer to a support structure that attaches the cannula to the guide.

The Court agrees with MDTech that, based on the specification, prosecution history, and dictionary definition, "cannula mount" cannot simply mean "anything." Rather, the Court concludes that this language contemplates and, thus, claims a piece or structure which is independent from the structures which are the guide and the cannula, and serves the function of connecting the two other structures. Thus,

the Court construes "a cannula mount affixing the cannula to the guide" to mean "*a structure or support which attaches or connects the cannula to the guide.*"[7]

2. "a manually operable charging member for moving the guide to the charged position against the urging of the coil spring"

Plaintiff argues that this term should be construed to mean "a manually operable charging member or mechanism that is used to create a charge or stored energy, the charging member or mechanism configured to move the guide to the charged position against the urging of the coil spring." MDTech's proposed construction is "a charging member operable by means of the hand for moving the guide to the charged position against the urging of the coil spring." The parties' primary disagreement about this term's construction is based on Plaintiff's inclusion of the word "mechanism."[8]

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7. The Court is not persuaded by Plaintiff's argument that defining this term as requiring a structure or support is the equivalent of improperly construing it as a means-plus-function claim. The Court is not holding that the structure or support must *only* be the structures identified in Fig. 1 and Fig. 5 as the cannula mounts (58 and 258), as would be the effect of a finding that it is a means-plus-function claim. The holding is merely that it must have some structure and cannot be just "anything."

8. In its brief and at the *Markman* hearing, Plaintiff also objected to MDTech's use of the phrase "operable by means of *the hand*," arguing that the term implies that the device can be

Cont'd

Indeed, both parties' proposed constructions add very little to the claim language, other than Plaintiff adding the word "mechanism" and MDTech making a point of excluding it.

In regards to this dispute, the detailed description of the invention in the patent describes the safety cap as the element that is retracted in order to move the guide against the spring, thereby compressing the spring and putting the device in the charged position. The dispute in this case is whether the safety cap or other structure that is used to move the device into the charged position can be described as a "mechanism."

MDTech objects to the inclusion of the word "mechanism" because, according to MDTech, "member" and "mechanism" are not interchangeable terms, and including "mechanism" improperly broadens the scope of the claim beyond the easy-to-use invention these patents describe. MDTech points out that the word "mechanism" appears only twice in the specification and, in those instances, only to describe the more complicated prior art upon which the patent sought to improve. ('797 patent, col. 1, l. 62-67 (describing prior art as disclosing "a complicated biasing mechanism") and col. 3, l. 8-12 (explaining that known biopsy instruments "incorporate

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Cont'd
operated by only one hand, which Plaintiff states is a possibility, but not a limitation. At the *Markman* hearing, counsel for MDTech clarified that MDTech was not seeking to impose a onehanded limitation, and, therefore, this is no longer a point of contention. Because the Court believes that "manually" does not require a definition, it includes "manually" and not "by means of the hand" in its construction of this term.

biasing mechanisms which are either complicated in construction or require undue force to operate")). In addition, MDTech argues that its position is supported by the dictionary definitions, which will be discussed below.

In support of its proposed construction, Plaintiff relies primarily on *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359 (Fed. Cir. 2002), in which the Federal Circuit held that the ordinary and customary meaning of the term "member" was not limited to a single component only but, instead, encompassed a multi-component structure. Plaintiff argues that, although both the Fig. 1 and Fig. 5 embodiments describe a "charging member" by reference to the safety cap, the absence of a multi-component "charging member" in the specification should not be used to narrow the ordinary and customary meaning of the term "member." In addition, counsel for Plaintiff argued at the *Markman* hearing that his argument was also supported by the fact that claim 5 of the '797 patent further defines the term "charging member" by including the following: "the charging member comprising a safety cap means for blocking inadvertent actuation of the release lever." ('797 patent, col. 12, l. 48-50.) Counsel argued that, under the doctrine of claim differentiation, this definition supports his argument that the "charging member" as used in claim 7 could not be limited to just the safety cap or otherwise just a single component.

The Court is not persuaded by Plaintiff's arguments and finds that the term "mechanism" is inconsistent with

the common and ordinary meaning of "member" to someone skilled in the art, as well as with what is disclosed in the patent specification. First, the Court finds that *CCS Fitness* does not support Plaintiff's proposed construction. At issue in *CCS Fitness* was the term "reciprocating members" as used in patents for an elliptical trainer exercise device. *CCS Fitness*, 288 F.3d at 1362. In the patents at issue in that case, the drawings for the preferred embodiments showed the reciprocating members as single-component, straight bars that connected the pedals of the device to a shaft and crank system near the front of the machine, allowing the pedals to have a circular motion as the user pushes up and down on them. *Id.* at 1362-63. In that case, the accused infringing device contained a curved-bar with multiple components that served the same purpose of allowing the circular motion. *Id.* at 1364. In reversing the district court's construction of "member" as being limited only to a single-component structure, the Federal Circuit held that both the technical meaning and the ordinary and customary meaning of "member" encompassed a "beam-like structure that is 'a single unit in a larger whole.'" *Id.* at 1367.

As an initial matter, *CCS Fitness* involved a different patent and is, of course, not directly controlling in this case. In addition, the term "mechanism" does not appear anywhere in the Federal Circuit's opinion in *CCS Fitness*. Rather, the Court held that the term "member" encompassed a multi-component beam, lever, or structure. Significantly, the Court consistently referred to the beam, lever, or structure in the *singular*, i.e., a

single structure that has multiple components. On the other hand, the term "mechanism" connotes a group of *independent* parts working together. Indeed, "mechanism" is defined as "1 a: a piece of machinery : a structure of working parts functioning together to produce an effect." Webster's Third New International Dictionary 1401 (1993); *see also* Merriam-Webster Online Dictionary, *www.m-w.com* (defining "mechanism" as "1:a: a piece of machinery."). On the other hand, "member" is defined as "4: a constituent part of a whole, as . . . d(2): an essential part of a framed structure, a machine, or a device." Webster's Third New International Dictionary 1408 (1993); *see also* Mirriam-Webster Online Dictionary, *www.m-w.com*, (defining "member as "4: a part of a whole."). A mechanism, therefore, is not commonly understood to be simply a single part that has multiple components; a mechanism itself has multiple parts. Nor can "member" and "mechanism" be treated as synonymous, as Plaintiff seemingly attempts to do.

Based on the Court's reading of *CCS Fitness*, it concludes that the case does not support Plaintiff's proposed construction, and Plaintiff has not pointed to any other source that would support the interpretation of "member" as including the alternate meaning of "mechanism." Indeed, as MDTech argues, the specification actually counsels that, in defining "member," the Court should err on the side of simplicity rather than on the side of complexity. The only references to "mechanism" in the specification relate to prior art, are accompanied by the term "complicated," and are the very types of elements that Baran asserts

he was attempting to remedy by making his invention more simple. Given that, and absent any other source to expand the meaning of "member" as it is used in claim 7, the Court cannot define "member" as including the alternate term "mechanism."

In addition, the argument Plaintiff raised at the *Markman* hearing based on the doctrine of claim differentiation does not convince the Court that it should add the words "or mechanism" to this claim language. According to Plaintiff, because claim 5 of the '797 patent further defines "charging member" as "comprising a safety cap means for blocking inadvertent actuation of the release lever," the term "charging member" in claim 7 cannot be limited to a single-component structure. Presumably, counsel for Plaintiff is contending that, because claim 5 employs the term "comprising," claim 5 describes a charging member that includes a safety cap but is not limited to just the safety cap.[9] According to Plaintiff, then, defining the term "member" in this case as only a single component renders the language in claim 5 further defining the "charging member" as comprising more than one element superfluous.

9. "'Comprising' is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim." *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501 (Fed. Cir. 1997). The term "comprising" is contrasted with the term "consisting of" in general principles of claim construction. "Consisting of" generally is interpreted as including the subsequent elements listed, but no more and no less.

As an initial matter, the defendant does not seek to limit the term member to a *single component* structure. At the hearing, counsel for MDTech said: "I'm not saying it has to be a single part. I mean, if it were two things welded together that moved in unison, I would consider that still a member." (Tr. at 89.) Rather, MDTech simply argues that Plaintiff's effort to expand "member" to include the far more complicated concept of a "mechanism" reaches too broadly, and effectively rewrites the claim.

Even if the Court were to resort to the doctrine of claim differentiation, moreover, its application would not compel the result Plaintiff espouses. Although claim differentiation can apply outside of the independent/dependent claim scenario, the Federal Circuit has "observe[d] that two considerations generally govern this claim construction tool when applied to two independent claims: (1) claim differentiation takes on relevance in the context of a claim construction that would render additional, or different, language in another independent claim superfluous; and (2) claim differentiation 'can not broaden claims beyond their correct scope.'" *Curtiss-Wright Flow Control Corp. v. Velan, Inc.*, 438 F.3d 1374, 1381 (Fed. Cir. 2006) (*citing Fantasy Sports Props v. Sportsline.com*, 287 F.3d 1108, 1115-16 (Fed. Cir. 2002)). The Federal Circuit has characterized this doctrine more generally as "the presumption that each claim in a patent has a different scope." *Id.* at 1380 (*quoting Versa Corp. v. Ag-Bag Int'l Ltd.*, 392 F.3d 1325, 1330 (Fed. Cir. 2004)). Further, the Court has described claim differentiation as a "narrow tool of claim construction." *Id.* at 1378.

In this case, the doctrine of claim differentiation simply does not compel the result Plaintiff espouses. Even if this Court construed "charging member" in claim 7 as including only a single component, it would not render the language in claim 5 superfluous. In that instance, such a construction would not limit the charging member in claim 7 to a component that includes a safety cap (the single component could be some other structure or part), even though claim 5 does require such a cap. As such, the language in claim 5 would not be superfluous. This Court, therefore, does not find that claim differentiation effects its analysis of this disputed language.

The Court notes, however, that, in finding that "member" does not encompass "mechanism," it only determines what "member" is *not*; it does not determine how it should be defined. For their part, the parties offer little guidance and, indeed, do not even attempt to define member.[10] Given that the parties do not seek to define "member," and that their sole dispute over this term is whether it could be defined to include "mechanism," the Court sees no need to further define this term.

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10. As noted at the *Markman* hearing:

> THE COURT: But, you don't even seek to define member, really, other than – what you seek to define is manually.
>
> MS. THOMPSON (counsel for MDTech): No, I seek to define member only insofar as to exclude the expansion that Plaintiffs put on it.

(Tr. at 88.)

Accordingly, the Court construes "a manually operable charging member for moving the guide to the charged position against the urging of the coil spring" pursuant to Plaintiff's proposed construction, absent the term "mechanism," as follows: "*a manually operable charging member that is used to create a charge or stored energy, the charging member configured to move the guide to the charged position against the urging of the coil spring.*"

3. "a release means for retaining the guide in the charged position"

The parties agree that this term should be construed as a means-plus-function claim limitation in accordance with Section 112, ¶ 6. As discussed above, construction of a means-plus-function claim involves a two-step process. First, the Court must identify the recited function that the "means" performs. *Omega Eng'g, Inc.*, 334 F.3d at 1321. Next, the Court must identify the corresponding structure that performs the recited function. *Id.*

a. Recited Function

In defining the recited function, MDTech argues that the word "release" preceding the means language must be considered and, therefore, the stated function is the means for retaining the guide in the charged position and releasing the guide from the charged position. In support of its argument, MDTech argues that every word in a claim must be given meaning, and that "release" cannot simply be ignored. This principle

must be followed here, according to MDTech, even though a clear function follows the term "means for" and even though the term "release" precedes the means language in this term. In support of its argument, MDTech cites *Cannon Rubber Ltd. v. The First Years Inc.*, 2004 WL 2095669 (N.D. Ill. Sept. 17, 2004), which will be discussed below.

Plaintiff argues that the function to be performed should only include the phrase following the word "for," i.e., that the function should be defined as "retaining the guide in the charged position." Plaintiff contends that when a function is expressly stated in a claim, it is impermissible to adopt a different function than the one stated. Further, Plaintiff argues that requiring the release function as well as the retention function here essentially would be importing limitations from the specification into the claim, which is also impermissible. According to Plaintiff, the word "release" is best understood in this claim as requiring that the retaining means element be releasable - i.e., that the structure performing the retaining function can subsequently be released.

The Court begins its analysis by looking to *Cannon Rubber*, a district court case upon which MDTech primarily relies. The patent at issue in *Cannon Rubber* disclosed a handheld breast pump for nursing mothers, and the district court was faced with the construction of the term "valve means mounted in the body for cyclically releasing the negative pressure which is generated in the inlet." *Id.* at *2. In that case, the patent

specification described the valve as serving two roles: when the handle to the pump was squeezed, the valve helped form a seal between the upper part of the pump and the milk-collecting vessel to maintain negative pressure within the upper part of the pump, thus causing the user to lactate; when the handle was released, the valve broke its seal, leaving an aperture so that the milk could flow through to the milk-collecting vessel below. *Id.*

Regarding the stated function of the disputed claim term, the plaintiff in that case argued that the word "valve" preceding the means language should be disregarded in defining the recited function. *Id.* at *4. The court rejected the plaintiff's various arguments for disregarding that term, explaining that "[i]t is well established that each word in a claim must have meaning." *Id.* (*citing Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp.*, 93 F.3d 1572, 1582 (Fed. Cir. 1996)). The court then looked at the common and ordinary meaning of the word "valve," finding that the term meant "any of numerous mechanical devices by which the flow of liquid, air . . . may be started, stopped, or regulated by a moveable part that opens, shuts, or partially obstructs one or more ports or passageways." *Id.* at *6. Based on that definition, the court defined the function of the claim term as "cyclically releasing the negative pressure which is generated in the inlet and regulating the flow of air through a passageway by opening, closing or obstructing the passageway." *Id.* (emphasis added.)

Applying the reasoning of *Cannon Rubber* to the instant case, MDTech argues that this Court should read the term "release" as informing the definition of the recited function, such that the function should be both retaining *and* releasing the guide. In response, Plaintiff takes issue with MDTech's reliance on *Cannon Rubber*, arguing at the *Markman* hearing that "the term valve was given ordinary and customary meaning, [it] wasn't interpreted [as] part of [a Section] 112, paragraph 6 analysis. And the Court did not look to the specification to identify the specific functioning of the valve." (Tr. at 60.)

First, the Court disagrees with Plaintiff's counsel's interpretation of *Cannon Rubber*. The court in that case clearly interpreted the term "valve" as part of its Section 112, ¶ 6 analysis, as evidenced by the fact that it first defined the recited function as being *both* the cyclical releasing of negative pressure *and* the regulating of the flow of air by opening, closing, and obstructing, then identifying the corresponding structures that performed both of those functions. The court specifically noted, after examining the specification and identifying multiple structures that perform the recited functions, that the term "'valve means' comprises a combination of structural components working together to complete the pressure cycle." *Id.* at *8.

One facial difference between *Cannon Rubber* and the present case is that Plaintiff in this case, unlike the plaintiff in *Cannon Rubber*, does not ask the Court to disregard "release;" rather he argues that "release"

does have meaning, and that it is best understood as meaning that the retaining means is releasable. The Court, however, does not find that to be a tenable interpretation. Had the patent drafter sought to convey a releasable retaining means, the drafter would have simply used the word "releasable" rather than "release." Viewing "release" to mean "releasable" in this context is simply too much of a stretch. Having failed to propose a tenable meaning of the term "release," therefore, Plaintiff is in a similar position in this case to the plaintiff in *Cannon Rubber*: Plaintiff essentially asks the Court to ignore the term "release."

This Court, like the court in *Cannon Rubber*, is faced with a means-plus-function clause that has a very clearly defined function ("for retaining the guide in the charged position") with prefatory language ("release") that, if used to inform the recited function, would suggest a different or additional function. This situation appears to present a conflict between two rules of claim construction. On one hand, to use the term "release" to inform the definition of the function arguably "impermissibly limit[s] the claim by adopting a function different from that explicitly recited," *Generation II Orthotics, Inc. v. Med. Tech., Inc.*, 263 F.3d 1356, 1364-65 (Fed. Cir. 2001); on the other hand, to ignore the term "release" would run afoul of the rule that "[w]e must give meaning to all words in [the] claims," *Exxon Chemical Patents, Inc. v. Lubrizol Corp.*, 64 F.3d 1553, 1557 (Fed. Cir. 1995), and, similarly, that "claim limitations defining the subject matter of the invention are never disregarded," *In re Sabatino*, 480 F.2d 911, 913 (CCPA 1973).

In *Cannon Rubber*, the court resolved this conflict with the statement that, "[e]ven where, as here, clearly functional language follows the word 'for,' the prefatory claim language preceding the word 'means' serves to at least partially identify the function of the recited means." *Cannon Rubber*, at *5. As support for that proposition, the court cited *Sage Products, Inc. v. Devon Industries, Inc.*, 126 F.3d 1420, 1427-28 (Fed. Cir. 1997). This Court's review of *Sage Products*, however, does not support that proposition. First, the Court in *Sage Products* did not identify this particular problem. In addition, in that case, although the Federal Circuit did require the recited means to perform two functions, the source for both of those functions, although contained in the prefatory language, also *followed* the means language in those claims or was defined in language that followed. *Sage Prods., Inc.*, 126 F.3d at 1427-48 (holding that the limitation "closure means . . . for controlling access" requires the means to perform the functions of "closing the slot means" and "controlling access to the slot means," where the claim itself describes that "closure means" as being "capable of moving to close access to said slot means.") In the least, there is a much weaker basis in this case than in *Sage Products* to read "release" into the stated function.

The Court, nonetheless, finds that it must give meaning to the term "release" in this claim. Absent another tenable interpretation, which has not been offered, the Court must assume that the patent drafter included this term for a reason. In this case, the only possible meaning the term "release" has in this claim is to better inform the function that the means must perform.

Interestingly, one of the definitions of "release" in its noun form includes both the retention and releasing function. Mirriam-Webster Online Dictionary, *www.m-w.com* ("6: a device adapted to *hold or release* a mechanism as required.")(emphasis added). In its verb form, it is defined as "1: to set free from restraint, confinement, or servitude." *Id.* As such, the Court identifies the function of this means-plus-function claim as "retaining the guide in the charged position and releasing, or setting free, the guide from the charged position."[11]

b. Corresponding Structure

The next step in a means-plus-function limitation is identifying the structure in the specification that corresponds to the recited function. A structure is corresponding "only if the specification or the prosecution history clearly links or associates that structure to the function recited in the claim." *Omega Eng'g, Inc.*, 334 F.3d at 1321 (*quoting B. Braun Med., Inc. v. Abbott Labs.*, 124 F.3d 1419, 1424 (Fed. Cir. 1997)). In this case, the '797 patent's detailed description of the invention explains the retention and the release of the spring guide as follows. As for the retaining function, the patent provides that, to convert the instrument from the discharged mode to the charged mode, "[t]he safety

11. Contrary to Plaintiff's argument, the identification of this function does not improperly import a limitation from the specification; it looks only to the ordinary and common meaning of "release," a term which the patentee chose to write into the claim.

cap 20 and the spring guide 18 are retracted in this manner until the latching projection 102 on the release lever 22 engages in the annular external shoulder 54 of the spring guide." ('797 patent, col. 7, l. 23-27.) Fig. 4A below shows the release lever 22 and latching projection 102 as they appear in the discharged mode. Similarly, in the single use embodiment, the patent states that conversion to the charged mode requires that "the latching projection 302 of the release lever 222 engages the external shoulder of the biopsy spring guide 218." (*Id.*, col. 10, l. 5-7.)

As for the releasing function, the patent explains that "the operator . . . actuates the instrument by depressing the finger rest 96 of the release lever 22, which is flexibly welded to the outer casing 12 as described hereinabove. Manipulation of the release lever raises the latching projection 102, disengaging it from the external shoulder 54 of the spring guide 18." ('*Id.*, col. 7, l. 61-67.) The single use embodiment is used "in precisely the same procedure" as the reusable embodiment. (*Id.*, col. 10, l. 14-16.)

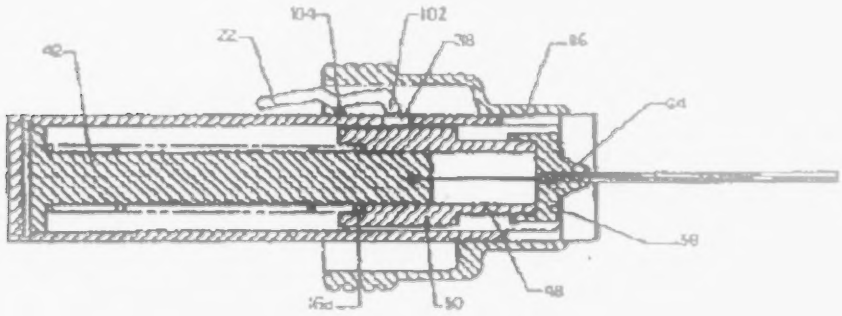

FIG. 4A

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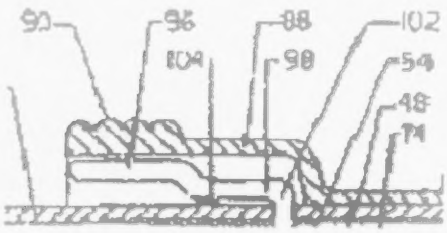
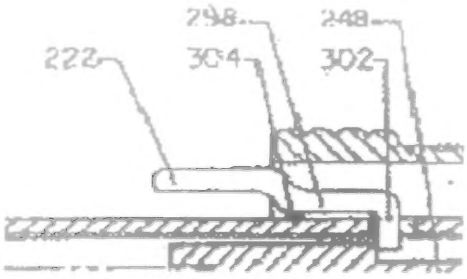
In turn, as shown to the right in a portion taken from Fig. 2, "[t]he release lever 22 comprises a finger rest 96 and a mounting section 98 maintained in spaced parallel planes by a connecting web 100 . . . Mounting section 98 is formed with a latching projection 102 at one end of the release lever and is flexibly secured to the outer casing with a spot weld 104." (*Id.*, col. 6, l. 25-32).

Likewise, the single use embodiment contains substantially similar features (with different corresponding numbers), as shown to the right in a portion of the illustration taken from Fig. 8. The description provides that "[t]he mounting section 298 of the release lever 222 is flexibly solvent-bonded to the outer casing at 304. (*Id.*, col. 9, l. 36-37.)



Based on the specification described above, the Court finds that the structures corresponding to the recited functions in this means-plus-function limitation are the following: (1) for the reusable embodiment (Figs. 1 - 4A), the release lever 22, including the latching projection 102, the finger rest 96, and mounting section 98, as well as the equivalents thereof; and (2) for the

single use embodiment (Figs. 5- 8A), the release lever 222, including the latching projection 302, the finger rest (not marked by a reference numeral), and the mounting section 298, as well as the equivalents thereof. All of these structures and their elements are specifically linked to the stated functions of retaining and releasing the spring guide, either in the description of the operation of the instrument or the detailed description of the structures themselves. As such, they are appropriately determined to be corresponding structures.



4. "biopsy actuator"

Turning to the other patent in suit, the '798 patent, the first disputed term of claim 2 (the only asserted claim) is "biopsy actuator." Plaintiff's proposed construction is "a mechanism for the removal of tissue." MDTech proposes that this term be defined to mean "the automated biopsy instrument 10 having an outer casing 12; an inner support rod 14; a coil spring 16; a biopsy spring guide 18; a safety cap 20; a release lever 22; and

a needle 24, as shown in Figure 1." In essence, MDTech's proposed construction defines the "biopsy actuator" as the "automated biopsy instrument"- i.e., the claimed invention.

In support of its proposed definition, MDTech relies solely on the prosecution history. According to the prosecution history, the examiner initially rejected claim 2 (originally claim 8 in the application) as being indefinite because it read "a biopsy actuator . . . *further* comprising . . .," even though the "biopsy actuator" itself had not been defined as having any structure. (Ex. 5 to MDTech's Br., GWB00609) (emphasis added). In response, the applicant amended the patent application by deleting "further" from the claim. (*Id.* at GWB00600.) MDTech seizes upon comments made in the remarks to this amendment where the applicant describes the invention as "comprising a cannula 66 and a *biopsy actuator* 10." (*Id.* at GWB00606) (emphasis added). In the specification of the '798 patent, however, reference numeral 10 refers to the "automated biopsy instrument" generally. ('798 patent, col. 5, l. 29-32.) The automated instrument 10 is further described as having the "seven principle elements" that MDTech seeks to use to define the "biopsy actuator."

At the *Markman* hearing, counsel for MDTech argued that the applicant used reference numeral 10 to refer to the biopsy actuator in order to overcome the examiner's finding that the claim was indefinite as originally drafted. In doing so, MDTech argues that the patentee acted as his own lexicographer and defined

"biopsy actuator" as "biopsy instrument," thereby incorporating all of the elements of the biopsy instrument.

As an initial matter, it is clear that MDTech's interpretation of the prosecution history is inaccurate. The applicant did not refer to the biopsy actuator using reference numeral 10 in *response* to the examiner's assertion that the claim was indefinite; he made that reference in the remarks section of the filing when he was providing a general description of the invention. The only mention of claim 8 (which ultimately became claim 2) in the amendment and response section was to indicate that "further" was deleted. MDTech is attempting to extrapolate a comment made in the remarks section and attribute a motivation for making that comment which is simply not there. For that reason, its interpretation must be rejected.

While the Plaintiff argues that the reference to numeral 10 in the remarks was just a mistake by the prosecuting attorney and should not be given any significance, this Court does not need to determine whether it should be characterized as a mistake, because the claim and the specification provide enough guidance for construing this term. MDTech's proposed interpretation is inconsistent with the claim and the specification and, therefore, regardless of whether the prosecuting attorney made a mistake or not, the one paragraph of the prosecution history upon which MDTech relies is given little weight compared to the rest of the intrinsic evidence that guides this Court.

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It is also clear that Plaintiff's proposed definition - "a mechanism for the removal of tissue" - is too broad and essentially repeats the introductory phrase of claim 2, which is "[a]n apparatus for acquiring biopsy specimens." Plaintiff also points out that "biopsy actuator" is further defined in claim 2 under subparts d) and e), which provide:

> d) said biopsy actuator comprising a second connector means for releasably and fixedly engaging the first connector means, wherein the first connector means and the second connector means are movable as a unit during acquisition of the biopsy specimen,
>
> e) said biopsy actuator comprising means for rapidly advancing the distal end of said cannula beyond the distal end of the stylet means to acquire a core biopsy specimen.

('798 patent, col. 14, l. 67 - col. 15, l. 8.) According to the claim language, therefore, the "biopsy actuator" includes at least a second connector means and a means for rapidly advancing the cannula. In addition, the Summary of the Invention section of the '798 patent describes the invention as "comprising a cannula and a biopsy actuator," (*Id.* at col 3, l. 43-44), and further explains that the biopsy actuator includes a stylet means, (*Id.* at col. 3, l. 47-50), a second connector, (*Id.* at col. 3, l.

58-63), a means for exposing the notch of the stylet and subsequently advancing the cannula over that notch, (*Id.* at col. 3, l. 64-67), and, in some aspects of the invention, a means for retracting the second connector (*Id.* at col. 4, l. 5-10) and for rapidly advancing the cannula (*Id.* at col. 4, l. 16-19). Further, the Detailed Description of the Invention indicates that an operator of the biopsy instrument "*actuates* the instrument by depressing the finger rest 96 on the release lever 22," which raises the latching projection such that "the stored energy of the biasing means or compressed coil spring 16 is released to drive the cannula 66 forward over the stationery stylet 60 and into the mass." (*Id.* at col. 8, l. 48-58) (emphasis added).

According to the claim and the specification, therefore, the "biopsy actuator," in descriptive terms and in the words of Plaintiff's counsel, constitutes the subparts of the biopsy instrument that make the instrument an automated rather than a manually operated device. (Tr. at 63). Although there is little in the specification that limits the biopsy actuator to something less than the entire biopsy instrument, it must be something more limited than the "apparatus" referred to in the introductory language to claim 2, and it at least does *not* include the cannula.

Based on the claim language and the specification, therefore, the Court defines "biopsy actuator" as "*a mechanism for putting the biopsy instrument in*

operating motion, other than by hand."[12] This construction is also consistent with the ordinary meaning of "actuator," which is defined as "one that actuates; *specifically* : a mechanical device for moving or controlling something." Merriam-Webster Online Dictionary, *www.m-w.com*; *see also* Webster's Third New International Dictionary 22 (1993) ("one that actuates; *specif*: any of various . . . mechanisms by means of which something is moved or controlled indirectly instead of by hand.")

5. "said stylet means being detachable from said cannula"

The Court addresses this term out of order because construction of this term aids the discussion of the remaining terms. The dispute as it relates to this term is over the word "detachable." Plaintiff's proposed construction is "the stylet is capable of being decoupled or disassembled from the cannula." MDTech's proposed construction is "the thin wire with a sharpened point is capable of being separated or withdrawn from the cutting cannula without loss or damage." At oral argument, counsel for MDTech agreed that "stylet" or

12. The Court rejects MDTech's belated argument, made for the first time at the close of the *Markman* hearing, that this definition would render the term "biopsy actuator" indefinite. The Court finds that the additional limitations placed on this term elsewhere in claim 2, where the term is first used, suffice, as construed by this Court, to provide a sufficiently definite structure to the actuating mechanism claimed.

"slender probe"[13] could be substituted for "thin wire with a sharpened point" and that "cutting" could be removed before cannula. (Tr. at 109.) The issue, therefore, is whether "detachable" requires that separation occur "without loss or damage."

In support of its argument that being "detachable" requires separation without loss or damage, MDTech relies on various case law, the specification of the '798 patent, and the dictionary definition of "detachable." The case on which MDTech primarily relies is *K-2 Corp. v. Salomon S.A.*, 191 F.3d 1356 (Fed. Cir. 1999), in which the Federal Circuit addressed the meaning of the term "permanently affixed" as used in a patent claim describing how an in-line roller skate base was connected to the boot. *Id.* at 1360-61. The asserted claim in that case contained the limitation that the boot be "permanently affixed" to the base, and the issue before the Court was whether a removable screw used in the accused device met the "permanently affixed" limitation. *Id.* In defining "permanently affixed," the Court first considered that the patentee distinguished prior art that included a "detachable" boot, noting that the term "permanently" was added to distinguish claims from the "detachable" boot disclosed in the prior art. *Id.* at 1364. The Court then addressed the difference between a

13. Plaintiff contends that the parties agreed to a stipulation that "stylet" would be defined as "slender probe." Counsel for MDTech did not remember that stipulation, however, and Plaintiff used "stylet" instead of "slender probe" in its proposed construction. As it does not appear to be a point of contention, the Court does not define "stylet" for purposes of this claim construction.

permanent and a removable connection, first considering what it considered a permanent rivet-made connection and a permanent single injection molded unit, and stating that:

> Likewise, were an adhesive laminate used to provide the permanent connection, that permanence too could be destroyed by breaking the structure apart. Screws, unlike rivets and laminates, are meant to be unscrewed, that is, to be removed. A rivet or a laminate, to the contrary, is meant to remain permanent, unremovable unless one is bent on breaking the permanent structure apart.

Id. at 1365 (citations to the record omitted). In affirming the district court's holding that "permanently affixed" required an unremovable connection, the Federal Circuit found that the removable screw in the accused device did not meet the limitation of the asserted claim and, thus, there was no literal infringement. *Id.* at 1365-66.

In this case, MDTech argues that the patentee focused on the "detachable" quality of the stylet and cannula in the reusable embodiment (depicted in Fig. 1), as contrasted with the permanently affixed quality of the stylet and cannula in the single use embodiment (depicted in Fig. 5). MDTech points to the fact that the specification describes the stylet of the reusable embodiment as being "detachably engaged" within the clevis 46 of the spring guide 18, but does not use the term "detachable" in relation to the stylet of the single

use embodiment. ('798 patent, col. 7, l. 41-43.)[14] Indeed, the single use embodiment is described as being assembled like the reusable embodiment, except that the stylet in the single use embodiment is "adhesively bonded" within the recess, and the cannula mount is "similarly secured" (i.e., with adhesive) within the bore. (*Id.*, col. 10, l. 24-27.) In addition to these arguments, MDTech also relies on a dictionary that defines "detachable" as "to separate especially from a larger mass and usually without violence or damage."

On the other hand, Plaintiff argues that MDTech's proposed construction is improper because there is nothing in the claim or specification that requires the limitation of "without loss or damage." Plaintiff points out that the specification, in describing the assembly of the instrument, explains that the stylet is telescopically or coaxially received within the cannula to form the needle in both the reusable and single use embodiments. ('798 patent, col. 7, l. 36-37; col. 10, l. 22-23.) Presumably, this reference indicates that, at some point, the stylet and cannula are separate and, therefore, detachable. Plaintiff argues that the claim does not specify *when* the stylet is capable of being decoupled or disassembled from the cannula, and that detachability does not occur during the normal operation of the instrument, but during the assembly or disassembly of the instrument. Plaintiff, however, does not address how they would be

14. For the sake of clarity, the Court notes that the 14 specification refers to the clevis 46 of the spring guide 18, but Fig. 1 appears to indicate that the clevis 46 is on the inner support rod 14, not the spring guide 18.

detached during disassembly. Finally, Plaintiff argues that there are dictionary definitions of "detachable" that do not include the words "without violence or damage," and that MDTech has selectively chosen a dictionary solely to support its proposed construction.[15]

After considering the parties' arguments, the Court concludes that MDTech has the better argument and that the term "detachable" as used in this claim requires separation "without loss or damage." The Court finds it significant that the specification only describes the stylet of the reusable embodiment as being "detachably engaged" within the clevis of the spring guide, ('798 patent, col. 7, l. 41-43), but specifically distinguishes the assembly of the single use embodiment by describing that the stylet is "adhesively bonded" within the recess of the base. (*Id.*, col. 10, l. 24-27.) The term "detachable" does not appear at all in the portion of the specification describing the single use embodiment. Further, "detachably" also appears in the specification in

15. Plaintiff also contends that MDTech misses the point by focusing on how the stylet is secured to the spring guide and how the cannula is secured to the cannula mount, because this claim focuses on the stylet's relation to the cannula, not to the other parts of the instrument. The Court is not persuaded by this argument. As MDTech put it, "[i]t will be appreciated that if the cannula and stylet are secured by adhesive, the stylet is not detachable from the cannula except upon the occurrence of 'violence or damage.'" (MDTech Br. at 21.) The stylet and the cannula need not be bonded to each other to conclude that the patentee did not intend them to be "detachable," it is enough that they are bonded to the instrument when the stylet is received within the cannula.

describing that the cannula mount is "detachably affixed" to the spring guide in the reusable embodiment, a connection that, in Fig. 1, is made by use of a screw thread, not a plug in or adhesively bonded connection.[16] The specification, therefore, refers to a piece being "detachably engaged" or "detachably affixed" where the piece is placed in the clevis or where a piece is connected by a screw thread; but it does not use that term when pieces are adhesively bonded or similarly secured. This distinction suggests that the patentee intended "detachable" to mean capable of removal or separation without breaking or causing damage through the necessary use of undue force.

This conclusion is further supported by the dictionary definition of "detachable," which is: "capable of being or designed to be detached : capable of being separated or withdrawn *without loss or damage.*" Webster's Third New International Dictionary 615 (1993) (emphasis added); *see also* Merriam-Webster Online Dictionary, *www.m-w.com* (not defining "detachable" separately, but defining "detach" as "1: to separate especially from a larger mass and *usually without violence or damage.*" (emphasis added)). Because the Court has relied on the same dictionaries throughout this opinion, Plaintiff's argument that MDTech has

16. The Court understands that the cannula mount being detachable from the spring guide is a separate feature than the stylet being detachable from the cannula; it only notes the use of the term "detachably" in that context to explore the patentee's understanding of that word's meaning as used in the '798 patent.

selectively used dictionaries to support its construction of this term is unavailing.

In addition, the Court notes that, although the Federal Circuit's decision in *K-2* is, again, not *directly* controlling on this issue because it involved a different patent, specification, and prosecution history (especially prior art distinctions that are not present in this case), it nonetheless reflects a similar understanding of the general concepts of detachability and permanent affixation. Although this Court's conclusion is based on the claim language and specification of the '798 patent specifically, it is at least consistent with the notion espoused in *K-2* that something is not detachable or removable if doing so requires breaking the permanent structure apart.

For the reasons stated above, therefore, the Court construes this term to be "*the stylet is capable of being separated or withdrawn from the cannula without loss or damage.*"

In so holding, the Court recognizes that this construction may exclude claim 2's coverage of the single use embodiment of the invention illustrated in Fig. 5. Indeed, this is a consistent area of dispute between the parties and, although it arises primarily in connection with the term "releasably engaging" (addressed next), this issue is also implicated by interpretation of the term "detachable." MDTech argues that claim 2 of the '798 patent was written only to cover the reusable embodiment of the invention, not the single use

embodiment. Specifically, MDTech contends that the use of the words "detachable" and "releasably engaging" in claim 2 demonstrates that the drafter intended this claim to cover only the reusable embodiment. According to MDTech, because the stylet and/or the cannula of the single use embodiment can be adhesively bonded or otherwise secured to the instrument, and because the cannula mount in that embodiment is connected to the spring guide with a peg and hole or adhesive connection, those pieces must be broken or subjected to undue force in order to detach or release them. MDTech argues that one skilled in the art would not understand "detachable" or "releasable" to require a user to damage or break the items in order to accomplish that task and, thus, that claim 2 is not written toward the single use embodiment.

Plaintiff counters by arguing that there is nothing in the patent that indicates that the patentee intended to give up an entire alternative embodiment when he drafted these claims, and that it would be improper to construe these claims in such a way that could produce that result. Specifically regarding the second connector means "releasably engaging" the first connector means, Plaintiff acknowledges that "the addition of an adhesive does create more of a bond," but that something adhesively bonded nonetheless can be pulled out. (Tr. at 72.) In addition, Plaintiff points out that all but one of the independent claims of the '798 patent (claim 18) use the term "releasably." As such, construing "releasably" as not covering the single use embodiment excludes all but one claim from covering that embodiment.

The Court agrees with MDTech that it is possible that claim 2 may not cover the single use embodiment and, even if the court's construction of "detachable" and "releasably engaging" produce that result, such a construction, though not the norm, is not improper. In describing the reusable embodiment, the specification clearly provides that "*[b]ecause the cannula mount 58 is detachably affixed to the spring guide 18*, the biopsy instrument 10 may *interchangeably* employ a needle having any one of several configurations well known in the art . . ." ('798 patent, col. 6, l. 46-53) (emphasis added). Although the single use embodiment can employ several needle configurations, it cannot do so *interchangeably*, a feature of the single use embodiment which is attributed to the fact that the cannula mount is detachably affixed to the spring guide. The specification does not contain similar language in connection with the single use embodiment.

In addition, contrary to Plaintiff's assertion, each claim of a patent does not have to cover every embodiment in the patent. *See Ventana Med. Sys. v. Biogenex Labs., Inc.*,473 F.3d 1173, 1181-82 (Fed. Cir. 2006) ("[E]ach claim does not necessarily cover every feature disclosed in the specification"). In this case, claim 18 of the '798 patent does not include the terms "detachable" or "releasably engaging" and, therefore, the Court's construction would not exclude claim 18's coverage of the single use embodiment. In addition, as MDTech points out, '798 is a continuation-in-part and does not have to cover everything that has already been covered by the '797 patent. Indeed, none of the claims

of the '797 patent contain "detachable," "releasably," or comparable terms and, therefore, would not exclude the single use embodiment. For that reason, the Court need not construe claim 2 to cover both the reusable and single use embodiments.

In addition, Plaintiff's remaining arguments are not persuasive. Plaintiff argues that the specification of the '798 patent explains that both embodiments have essentially the same operation with only small differences. ('798 patent, col. 9, l. 41-60.) ("[T]he principles of operation [of the reusable and single use embodiments] are virtually identical.") Plaintiff contends that this implies that both embodiments function in a "releasably engaging" manner. As noted above, the specification also expressly states that the reusable embodiment can interchangeably employ various needle sets because the cannula mount of that embodiment is "detachably affixed" to the spring guide, a feature that is not disclosed in relation to the single use embodiment. In addition, while the specification may state that both embodiments have essentially the same operation, it also explains that:

> Assembly of instrument 210 [the single use embodiment] is quite similar to assembly of instrument 10 [the reusable embodiment], as described hereinabove. *However*, in this instance, the proximal end 282 of the stylet 26[6] is *adhesively bonded* within the recess 246, and the base 262 of the cannula mount 258 is similarly secured within the bore 255*a*.

(*Id.*, col. 10, l. 22-27) (emphasis added.) In addition, while the cannula of the reusable embodiment is described as being secured "in any suitable manner," (*Id.*, col. 6, l. 35-37), the specification describes that the cannula of the single use embodiment "may there be secured by means of adhesive (not shown)." (*Id.*, col. 10, l. 14-15.) These distinctions are crucial, and they may well remove the single use embodiment from the coverage of a claim that describes an instrument with a "detachable" stylet or a cannula mount that is "releasably engaging" with the spring guide.

Finally, Plaintiff's cite to *Micro Chemical, Inc. v. Great Plains Chemical Co., Inc.*, 194 F.3d 1250 (Fed. Cir. 1999) is unavailing. In that case, the Federal Circuit explained that "[w]hen multiple embodiments in the specification correspond to the claimed function, proper application of § 112, ¶ 6 generally reads the claim element to embrace each of those embodiments." *Id.* at 1258. This cite, however, does not support Plaintiff's argument because it relates specifically to a means-plus-function analysis, namely a court's identification of structures in the specification that correspond to a recited function. Here, the Court is not identifying structures that correspond to the recited function in a means-plus-function clause, it is using ordinary claim construction principles to interpret a claim term, even though its construction may exclude that claim's coverage of an alternative embodiment. The Court, therefore, is not persuaded that it must give these disputed terms a construction that results in claim 2 covering the single use embodiment.

6. "said biopsy actuator comprising a second connector means for releasably and fixedly engaging the first connector means"

The Court also addresses this disputed term out of order because, as will be discussed below, interpretation of this term affects the interpretation of "first connector means," addressed next. The primary dispute as it relates to this term is whether it must be construed as a means-plus-function clause or whether it should be interpreted according to the standard rules of claim construction. MDTech argues that this term should be interpreted as a means-plus-function limitation, and that the corresponding structure is the quarter turn male thread 56 of the spring guide 18.[17] Plaintiff argues that ordinary principles of claim construction apply, and that this term should be defined as "the biopsy actuator comprising a second connector, which is anything that connects, the second connector being capable of being releasably and fixedly engaged with the first connector."

The first question the Court must resolve is whether the use of the term "connector" recites sufficient structure for performing the recited function to overcome the presumption that the drafter intended to invoke Section 112, ¶ 6, a presumption triggered by the

17. Because MDTech argues that claim 2 covers only the reusable embodiment of the invention, it only identifies structures that correspond to the structures of Fig. 1, not Fig. 5. Put another way, it argues that no structure in Fig. 5 performs the recited function.

use of the word "means". *Rodime*, 174 F.3d at 1302. MDTech argues that a person of ordinary skill in the art would not have understood "connector" to perform both the functions of releasably and fixedly engaging; specifically, MDTech contends that "connector" is commonly understood as only performing the function of engaging or joining, not releasing. According to MDTech, absent evidence that the patentee intended to act as his own lexicographer and define connector as also performing a releasable function, the term "connector" does not recite sufficient structure to perform the recited functions and this clause must be given a means-plus-function limitation.

Plaintiff argues that the term "connector" is commonly understood as a structure that is inherently capable of releasably and fixedly engaging another mating connector. Plaintiff gives examples in the field of medicine that include mechanical connectors (for fluid transfer), electrical connectors (for monitoring vital signs), and computer connectors (for imaging equipment). Plaintiff contends that, in those examples, the connectors are capable of being removed or released after they have been fixedly engaged with the other connector.

The problem with both of the parties' positions regarding this term is that they are too extreme. MDTech essentially argues that *no* connectors are capable of being released after they engage another connector (i.e., that all connectors form permanent connections), and Plaintiff argues that all connectors are

capable of being released. If the Court accepted MDTech's proposed construction, then this claim would be limited only to the precise structure in Fig. 1 - the quarter turn male thread on the spring guide - that performs this function in that one embodiment. That construction is too narrow. While it is true that some connectors may form a permanent connection and cannot be released, there are many aside from the screw-in cannula mount depicted in Fig. 1 that are capable of being released. For example, at the *Markman* hearing, the Court suggested that a hooking mechanism would operate as a connector that both fixedly engages and is releasable. (Tr. at 104.) MDTech's construction is improperly limiting.

The relevant dictionary definition of "connector" is "2: something that connects: as **a:** a flexible tube for connecting the ends of tubes **b:** a railroad coupling **c:** (1): a device for detachably connecting flexible electrical conductors together . . ." Webster's Third New International Dictionary 481 (1993). In turn, "connect" is defined as "1: to join, fasten, or link together usually by means of something intervening." *Id.* at 480. The examples of connectors provided in the dictionary definition, as well as those offered by Plaintiff, all describe a connector that can be later released. Indeed, one of the definitions included the term "a device for *detachably* connecting," which, although it is in the context of flexible electrical conductors, suggests that the term is not as limited as MDTech suggests.

On the other hand, Plaintiff contends that "connector" should be defined as "anything that connects," but ignores the language of the claim that requires the connector to both fixedly and releasably engage. While some connectors are capable of being released, Plaintiff does not offer anything to support the contention that a person of ordinary skill in the art would have understood that *all* connectors are capable of being released. The definition of "connect" includes the words "join, fasten, or link together" which imply both permanent and non-permanent connections (or connections that can be separated with and without loss or damage). Given that the claim was drafted so that the connector could both fixedly and releasably engage, this term must be construed to reflect the language chosen by the drafter.

For the foregoing reasons, the Court first concludes that "second connector means" recites sufficient structure to perform the stated functions, thereby rebutting the means-plus-function presumption. In addition, however, the Court does not accept Plaintiff's proposed construction of "connector" as "anything that connects." The claim describes a connector that is capable of being released after engaging, and the Court's construction must take into consideration this language chosen by the drafter. In determining how to construe the limitation of being "releasably" engaged, the Court looks to the previous term because the patentee used the same term in the specification - "detachably" - in describing how the cannula mount connects to the spring guide as he did in describing how

the stylet connects to the spring guide (or inner support rod, *see infra*, n. 13). Because the specification describes the cannula mount as being "detachably affixed" to the spring guide, it appears the patentee wrote the claim term "releasably engaging" with a similar meaning in mind. For the reasons stated in the previous term, the Court interprets the term "releasably" as requiring separation without loss or damage.

Accordingly, the Court construes this term to mean "*the biopsy actuator comprising a second connector, which is anything that can connect and be released without loss or damage, the second connector being capable of being releasably and fixedly engaged with the first connector.*"[18]

7. "said proximal end having a first connector means secured thereto"

Like the preceding term, the dispute in interpreting this term concerns the phrase "first connector means." Plaintiff's proposed construction for "first connector means" mirrors his proposed construction for "second connector means" - "anything that connects" - such that the entire term should be construed to mean, "said proximal end having a first connector, which is anything that connects, secured thereto." In its claim construction brief, MDTech originally proposed the

18. Once again, the Court acknowledges that this construction of claim 2 may exclude coverage of the single use embodiment, but concludes that such a construction is not improper for that reason alone.

construction, "the proximal end of the cutting cannula includes a first means to connect." At the *Markman* hearing, however, MDTech changed its proposed construction to defining this term as having a means-plus-function claim limitation under Section 112, ¶ 6. (Tr. at 107.) According to counsel for MDTech, the change occurred in order maintain consistency with MDTech's position that the phrase "second connector means" also constituted a means-plus-function claim and that the first connector means "would inevitably be that which communicates with the structure that is called for in the second connector means." (*Id.*) The structure MDTech identifies as correlating to the function of the "first connector means" is the cannula mount 58, which contains a female quarter turn thread 74 that interacts with the male quarter turn thread on the spring guide (the second connector means, according to MDTech).

For the reasons stated in connection with preceding term, the Court does not find that this is a means-plus-function clause, but it also does not find that "first connector means" can be defined simply as "anything that connects" because the first connector necessarily interacts with the second connector, which must be capable of being released. Therefore, the Court construes this disputed term as "*said proximal end having a first connector, which is anything that can connect and be released without loss or damage, secured thereto.*"

IV. CONCLUSION

For the reasons articulated in this opinion, the Court construes the disputed terms of the patents-in-suit as follows:

For the disputed terms in **claim 7 of the '797 patent**:

TERM	CONSTRUCTION
a cannula mount affixing the cannula to the guide	a structure or support which attaches or connects the cannula to the guide
a manually operable charging member for moving the guide to the charged position against the urging of the coil spring	a manually operable charging member that is used to create a charge or stored energy, the charging member configured to move the guide to the charged position against the urging of the coil spring
a release means for retaining the guide in the charged position	Means-plus-function claim in which the function is "retaining the guide in the charged position and releasing, or setting free, the guide from the charged position." The structures

	corresponding to this function are: (1) for the reusable embodiment (Figs. 1 - 4A), the release lever **22**, including the latching projection **102**, the finger rest **96**, mounting section **98**, and connecting web **100**, as well as the equivalents thereof; and (2) for the single use embodiment (Figs. 5- 8A), the release lever **222**, including the latching projection **302** and the mounting section **298**, as well as the equivalents thereof

For the disputed terms in claim 2 of the '798 patent:

TERM	CONSTRUCTION
biopsy actuator	a mechanism for putting the biopsy instrument in operating motion, other than by hand
said stylet means being detachable from said cannula	the biopsy actuator comprising a second connector, which is anything that can connect and be released without loss or damage

said proximal end having a first connector, which is anything that can connect and be released without loss or damage, secured thereto	the biopsy actuator comprisinga second connector, which is anything that can connectand be released without loss or damage, the second connector being capable of being releasably and fixedly engaged with the first connector
said proximal end having a first connector means secured thereto	said proximal end having a first connector, which is anything that can connect and be released without loss or damage, secured thereto

IT IS SO ORDERED.

/s/

KATHLEEN McDONALD O'MALLEY
UNITED STATES DISTRICT JUDGE

Dated: September 25, 2007